Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
(301) 827-6860

Dear FDA:

Petition to the Food and Drug Administration to enforce the single-use requirement for all Microkeratomes and their components used for LASIK (in accordance with existing regulations) Or to place a moratorium on their use (a partial or full withdrawal of approval).

The scope of this petition involves ALL Microkeratomes that currently have or are in the process of obtaining FDA 510K approvals for use in elective refractive eye surgery.

My hope is that the FDA and CDC, and any other appropriate regulatory authorities investigate and stop harmful patient practices as soon as possible. As many as eight million patients have had LASIK so far.

A prior Petition titled "Petition to the Food and Drug Administration regarding Medical Devices used for Elective Refractive Eye Surgery with Premarket Approvals (PMAs)" is hereby incorporated in this petition and included in Appendix A (All words, information, and/or references, etc.). That Petition was submitted by Dominic Morgan and is hereby incorporated by reference. http://www.lasiksucks4u.com/index.php?option=com_content&task=view&id=21&Itemid=30

The above petition supports this petition with additional references, examples, bases, reasons and potential actions for the FDA to consider.

If additional information, separate comments or any other modification to this submission is required to comply with the FDA's procedures, please contact the Petitioner as soon as possible. The undersigned hereby petition the FDA to change or cancel a regulation, or to take other action as outlined in the FDA's published procedures (http://www.fda.gov/opacom/backgrounders/voice.html).

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1. Statement of grounds

Each of these medical devices are regulated by the FDA as Class I or Class III medical devices. A license for single-use only procedure to perform the procedure may ONLY be obtained from the manufacturers with the purchase of each single-use disposable blade.

Examples of some of the Devices (and their components) included in the Scope of the Petition are:

> 1.1. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=20344
> ELECTRO-KERATOTOME, LINE-OPERATED
> STORZ INSTRUMENT CO.
> 510(k) Number K760726
>
> 1.2. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=103724
> HANSATOME MICROKERATOME
> CHIRON VISION CORP.
> 510(k) Number K972808
>
> 1.3. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=3521
> Device Name
> HANSATOME MICROKERATOME
> BAUSCH & LOMB, INC.
> 510(k) Number K010260
>
> 1.4. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=104686
> Device Name
> AUTOMATED DISPOSABLE KERATOME (ADK)
> LASERSIGHT TECHNOLOGIES, INC.
> 510(k) Number K974004
>
> 1.5. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=106705
> ONE UP DISPOSABLE KERATOME HEAD
> MORIA, INC.
> 510(k) Number K981742
>
> 1.6. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=109677
> MICROKERATOME, MODEL MK-2000
> NIDEK, INC.
> 510(k) Number K990900
>

1.2 Consistency with FDA's Goals.

The benefits of this petition outweigh the costs by effectively utilizing the limited FDA resources in an area where they are most needed to meet the goals of the FDA, Assuring Medical Product Safety, and protecting the Public Health (http://www.fda.gov/ope/FY03plan/default.htm). The following statements provide the basis for the benefits of this petition. The costs would be based on which agencies and what specific actions are taken based on this petition.

"Consumers spend $326 billion annually in the U.S. on medical products. An estimated 1.3 million people are accidentally injured by medical therapy in the U.S. each year, and as many as 100,000 die as a result of preventable medical errors. FDA must be vigilant in monitoring the production, distribution and use of these products because FDA's presence raises the likelihood that public health and safety problems associated with these products will be addressed and because it is critical to citizen safety."

"To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use. "

"FDA's three primary strategies for ensuring medical product safety are to: a) enhance global vigilance over product manufacturing and distribution; b) strengthen and focus domestic industry monitoring; and, c) expand and automate the systems which report on adverse events associated with the use of medical products. "

The FDA's goals are consistent with preventing injury and protecting the Public Health. Has the FDA ignored or even endorsed another potential Public Health Crisis (e.g., breast implants)? "A weakened FDA can only move slowly and with uncertainty. Consumer confidence in the Agency suffers, and real health and safety risks may grow."
http://www.fda.gov/ope/fy03plan/goals3.html

* Reduce the risk of medical devices and radiation-emitting products on the market by assuring product quality and correcting problems associated with their production and use."
(http://www.fda.gov/ope/fy03plan/goals.html)

1.3 Legal Basis for this Petition

The Petitioner makes a public demand that the Food and Drug Administration (the leading U.S. public health regulatory agency) assert its authority and supremacy in protecting the Public Health.

The Petitioner acknowledges that the FDA does NOT regulate the practice of medicine. The Petitioner further acknowledges that an "off-label" use of any device where benefits clearly outweigh risks may constitute the practice of medicine. However, practice of medicine does not allow anyone, including medical doctors, to break Federal or State laws. Furthermore, any user of these Class I devices (whether licensed physician or not) who violates the labeling of these devices unnecessarily exposing patients to a non-Prudent degree of risk, does not provide informed consent, and therefore, is not practicing medicine by definition. Thus, these practices are within the regulatory authority of the FDA.

The Petitioner asserts that when used in LASIK surgery, every patient MUST receive new microkeratome components (e.g., blades and cannulas), regardless of whether the device is operated by a physician, or a technician working under the supervision of a physician. Microkeratome components necessarily come into contact with blood and infectious corneal tissues. As such, their reuse is not practice of medicine, or even within the Standard of Care for any licensed physician, for any medical procedure, including LASIK. Moreover, if sterilization of Microkeratome blades and components is not performed at all, or is conducted by third parties whose motives are mainly

economic (not necessarily medical) then this also falls under the authority of the FDA. Finally, sterilization techniques commonly used (when they are used) are not effective with regard to HIV/Aids and other infectious diseases (let alone Creutzfeldt-Jakob Disease prions), historically an overriding public health concern which requires these components be used once and only once, then disposed of as hazardous medical waste. Accordingly, the Petitioner concludes that there is NO patient benefit for reuse of these device components, but instead, a very high potential for harm.

There are multiple additional legal bases for this petition because the Microkeratomes are regulated by the FDA as Class I medical devices for use in refractive eye surgery (commonly referred to as LASIK).

1.3.1 In general, the reuse or reprocessing of single use devices on multiple patients is a serious concern (see http://reform.house.gov/UploadedFiles/121605%20FDA%20Medical%20Device%20Letters.pdf).

Reuse also appears to be an off-label use or even violation of the FDA approval. Worse yet, the patients are exposed to the contaminated blades without resterilization. I think patients should be properly educated and informed prior to having LASIK surgery.

In light of present day Medical ethics, patients should be given true informed consent by a licensed medical professional (e.g., the M.D. Ophthalmologist surgeon explaining the true risks to physical and mental health). Unlicensed sales people who may be dressed to look as if they are medical professionals (e.g., wearing white lab coats) should not be allowed to explain things as their information may be incorrect and they may mislead patients.

Reusing a microkeratome blade used on another patient is not prudent and far too risky for patients. No patient should be subjected to a reused medical device that is labeled single use, and disposable even if the patient has informed consent. Reusing blades without patient informed consent violates many medical ethical principles including HHS IRB guidelines (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm), The Declaration of Helsinki "It is the mission of the physician to safeguard the health of the people" (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j6), the Belmont Report "Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. " (see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) and the THE NUREMBERG CODE "The voluntary consent of the human subject is absolutely essential." "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5).

1.3.2 The FDA does Not regulate the practice of medicine, but the FDA does regulate all users and practitioners of these devices. Not everything that a medical Doctor does is considered the practice of medicine. Being a licensed medical Doctor does Not allow a person to break Federal or State laws. An off-label use of a device explicitly for the potential benefit of a patient (where the benefit clearly outweighs the risk) would be considered a legitimate practice of medicine. However, when there is no patient benefit and/or the risk outweighs any benefit, then Not following the FDA labeling does Not constitute the practice of medicine By definition. Part of the definition of the

practice of medicine is to put the patients' best interests ahead of those of the Doctor. Any practitioner or user of these Class I devices (whether or Not he/she happens to be Doctor) who uses them in an unnecessarily risky way (including committing an assault) or who does Not provide informed patient consent would be under the FDA's regulatory authority.

Two Doctors in CA admitted to reusing a single blade on multiple patients and were placed on probation by the medical board, and I believe the penalty should be higher than this decision.

"LaserVue reused microkeratome blades among patients rather than sterilizing or replacing them. Former patients may have been exposed to infectious diseases such as HIV or Hepatitis. "
"Class Action o/b/o 2,700 former LaserVue patients. In a settlement to an investigation brought by Medical Board of California (MBC), defendants admitted that their protocol was to rinse and reuse a blade on up to 4 eyes. MBC concluded that defendants departed from standard of care and placed them on probation."
(see
http://www.lasikinfocenter.net/Webpages/Ongoing%20Litigation%20Against%20RS%20Webpage.htm.)

1.3.3 The Petitioner believes that the potential risks versus possible benefits assessment favor the Actions proposed in this petition and are consistent with the FDAs own objectives including Healthy People 2010. "The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life."
(http://www.fda.gov/OHRMS/DOCKETS/98fr/062502c.pdf).

1.3.4 Section 522(a) states that " In General.--The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class I device the failure of which would be reasonably likely to have serious adverse health consequences" (http://www.fda.gov/cder/guidance/105-115.htm#SEC.%20212).
The FDA authority to protect the Public from injury and the Public Health in general is based on section 522 (21 U.S.C. 360l). The CDRH has recorded that the failure of these devices has caused serious adverse health consequences

1.3.5 Under the FDA's authority with the Federal Food Drug and Cosmetic Act and all rules and regulations promulgated or annexed therein, including, but not limited to section 515(d) (g), 520(e) (q) and (r), 21 CFR 801.109, 21 CFR 803.5, 21 CFR 803.10, 21 CFR 814.82, 21 CFR 814.84, 21 CFR 814.39, and the FOOD AND DRUG ADMINISTRATION MODERIZATION ACT OF 1997, the Petitioner ask the FDA to act and to implement the enclosed Actions.

1.3.6 Title 21 et seq., Title 45 et seq., and the Good Manufacturing Practices act, and other Federal Laws may have been violated by the practitioners who used these devices.

1.3.7 FDA regulations state that the FDA may require the submission of the adverse safety and effectiveness data, as described in the Class I summary or citation under title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts
(http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm).

(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). Many adverse events are Not reported.

1.3.8 The FDA is mandated to assure Medical Product Safety. "To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use" (http://www.fda.gov/ope/fy03plan/goals3.html).

The FDA does consider petitions (http://www.fda.gov/opacom/backgrounders/voice.html) and comments for the development of future policy (http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm) and has authority to change that policy under Title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.100).

1.3.9 The American Academy of Ophthalmology has supported banning a device (bottle rockets) that since 1995 due to it causing eye injuries similar to those caused by elective refractive eye surgery. From July 1990 to December 1994, for instance the total number of serious eye injuries from all causes reported to the United States Eye Injury Registry (USEIR) was 4,575 cases (Serious Eye Injuries Associated With Fireworks- United States, 1990-1994 MMWR Vol. 44/No. 24, June 23, 1995, pp. 449-52; Center for Disease Control MMWR journal). On average over that 4 ½ year time period, that amounts to ~1,017 eye injuries per annum. Based on public information that over a million LASIK operations alone are performed every year and the percentage of those operations causing serious eye problems, the number of serious eye injuries per annum of elective eye surgery far exceeds all other causes.

1.3.10 The Federal Government CAN enforce Federal law even when licensed Doctors violate it.

The physicians can use each microkeratome blade ONLY once (one eye only) because Bausch & Lomb (and other microkeratome manufacturers) ONLY license the physician for a single-use only procedure. Only physicians are licensed to purchase this device under Federal law so any other use by the physician would be a violation of that same Federal Law. The FDA and the CDC KNOWS that LASIK surgeons are violating this licensing agreement by reusing these single use blades.

See attached Exhibit A: "Hansatome Microkeratome DRAFT 12-14-2000 Operator's Manual".
"Hansatome Microkeratome DRAFT 12-14-2000 Operator's Manual"
"Bausch & Lomb Surgical is the owner of U.S. Patent No. 4,840,175. "
"A license for single-use only procedure under U.S. Patent No. 4,840,175 to perform the patented procedure claimed in said patent may be obtained from Bausch & Lomb Surgical with the purchase of each single-use Bausch & Lomb Surgical AccuGlide disposable blade. U.S. Patent Nos. 5,624,456; 5,772,675; 6,007,553; 6,042,594; and 6,051,009. Date effective November 2000".
"Caution: Federal Law (U.S.A.) restricts this device to sale, by or on the order of, a physician".

The FDA requires that the device be designed and used to "eliminate or reduce risks as far as possible (inherently safe design and construction)" (see Exhibit B, "CHECKLIST OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS OF MEDICAL DEVICES DIRECTIVE, #2. Essential Requirements). Thus, The Doctor is also required to follow the procedures for use of the device (including using the blades ONLY once and cannulas) to also eliminate and reduce risks

as far as possible. These risks include permanent patient injury (which happened to me and at least one other patient of The Doctors). Note particularly item 4 below where it indicates that the device MUST NOT be adversely affected that it jeopardizes patient safety "when the device is subjected to the stresses which can occur during normal conditions of use."

1.3.11 The same laws used for other recalls can be applied to the microkeratomes, the blades and cannulas. Do Not allow them to be used anymore just like the contact lens solutions and cadaver tissue that has harmed the public health.

Two recalls recently by the FDA and the CDC- one for eye drops that spread fungus, and one for tissue that was Not properly screened. BOTH of these problems are obviously caused by the reuse of microkeratome parts but the FDA and CDC are still deciding and monitoring the problem. I sent peer reviewed literature showing that the problems caused by blade reuse have been studied with unethical research and without informed consent from patients.

Why aren't LASIK patients now told to get screened too?

1.3.12 Exhibit C is a letter from a LASIK surgeon named Dr. Glass who specifies that "Reusing microkeratome components that come into contact with blood or the cornea on multiple patients is not within the practice of medicine for patients in the United States let alone within the standard of care for any Medical Doctor (for any medical procedure including LASIK). There is NO patient benefit for reuse and there is a very high risk of harm to the patient. "

Just because a physician does something during a surgery does Not mean that it constitutes the practice of medicine. The FDA can regulate anything that does Not constitute the practice of medicine and obviously any violation of the FDA labeling or Federal law does Not constitute the practice of medicine.

"Reusing a microkeratome blade used on another patient is not prudent and far too risky for patients. No patient should be subjected to a reused medical device that is labeled single use, and disposable even if the patient has informed consent. Reusing blades without patient informed consent violates many medical ethical principles including HHS IRB guidelines (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm), The Declaration of Helsinki "It is the mission of the physician to safeguard the health of the people" (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j6), the Belmont Report "Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. " (see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) and the THE NUREMBERG CODE "The voluntary consent of the human subject is absolutely essential." "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5). "

As a patient PERMANENTLY injured for life by a licensed medical Doctor, I believe that in addition to obviously breaching medical ethics, reusing blades is also a heinous and barbaric crime.

If this was committed against multiple individuals would this would constitute a serial assault and a serial breach of Federal and State laws?

1.3.13 Patients were coerced deceptively into paying money for something that was known to permanently damage patients in 100% of cases. The flap never heals after LASIK and there is NO KNOWN physical benefit to the cornea from LASIK. Instead the cornea is permanently injured by LASIK. Standard of care requires that Patients MUST HAVE true informed consent (see Exhibit C).

2. Reasons for This Petition

The evidence indicates that the practitioners do Not use these Class I medical devices prudently and took a non-Prudent degree of risks with patients physical and mental health. For instance, medical Doctors admitted Not properly sterilizing microkeratome blades and Not using NEW microkeratome components. This would be a violation of the labeling for a single-use, disposable device.

My hope is that the appropriate government agencies (e.g., the FDA and CDC), and any other appropriate regulatory authorities investigate and stop harmful patient practices as soon as possible. As many as eight million patients have had LASIK so far.

Has the FDA working group or the CDC reached any conclusions yet about whether Doctors can violate Federal laws?

Why does the Federal Government Not enforce Federal law when licensed Doctors violate it to make MORE money by injuring patients unnecessarily?

The physicians can use each microkeratome blade ONLY once (one eye only) because Bausch & Lomb (and other microkeratome manufacturers) ONLY license the physician for a single-use only procedure. Only physicians are licensed to purchase this device under Federal law so any other use by the physician would be a violation of that same Federal Law. The FDA and the CDC KNOWS that LASIK surgeons are violating this licensing agreement by reusing these single use blades.

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#2. Essential Requirements). Thus, The Doctor is also required to follow the procedures for use of the device (including using the blades ONLY once and cannulas) to also eliminate and reduce risks as far as possible. These risks include permanent patient injury (which happened to me and at least one other patient of The Doctors). Note particularly item 4 below where it indicates that the device MUST NOT be adversely affected that it jeopardizes patient safety "when the device is subjected to the stresses which can occur during normal conditions of use."

Two recalls recently by the FDA and the CDC- one for eye drops that spread fungus, and one for tissue that was Not properly screened. BOTH of these problems are obviously caused by the reuse of microkeratome parts but the FDA and CDC are still deciding and monitoring the problem. I sent peer reviewed literature showing that the problems caused by blade reuse have been studied with unethical research and without informed consent from patients.

Why aren't LASIK patients now told to get screened too? I got screened on my own after I found out.
Unlike bone, tendon and other tissues, the eye and BLOOD are considered highly infectious. The microkeratome then inserts this HIGHLY infectious tissue into the eye of any other patients it comes into contact with.

With LASIK, THERE IS NO SCREENING AND NO STERILIZATION AT ALL FOR THIS TISSUE that is spread between patients!

The entire inside of the microkeratome must get splattered with tissue and blood (it's a blade rotating at very high speeds)- the cleaning instructions indicate it does.
This has been well known by the CDC and the FDA and readily admitted by many Doctors!

If a Doctor took cadaver tissue without screening, the FDA and the CDC would certainly act. The Petitioner is merely asking for the same to be done for reusing microkeratome blades.

Reusing blades increases the risks of a number of problems including DLK which has all of these symptoms. If someone has had LASIK, then how do you even know if they have this infection if they have all these symptoms for life anyway?

Doctors also have to get informed consent from patients.

Outbreak of Eye Fungus Prompts FDA Warning
>Symptoms include redness, pain, tearing, increased light sensitivity, blurry vision, and discharge or swelling. The FDA warned that contact lens users who experience any of these symptoms should immediately remove the lenses and call a doctor.
http://www.medpagetoday.com/ProductAlert/DevicesandVaccines/tb/3072
>The U.S. Food and Drug Administration says that it and the federal Centers for Disease Control and Prevention believe the risk for infection is low. Even so, the FDA recommends that hospitals and physicians who engrafted the suspect material contact patients around the country and advise them of the need to be tested. The FDA has also ordered the recall of bone, tendon, skin, heart valves and other tissues — known as "allografts" — distributed by the company at the heart of the alleged multimillion-dollar scheme, Biomedical Tissue Services of Fort Lee, N.J.

>Grafts of human tissue may be diseased
>94 who got stolen body parts told to get tested
>The unidentified patients, among thousands in a growing nationwide horror story, have been advised to undergo testing for HIV/AIDS, syphilis and hepatitis B and C because the material grafted into them was not properly screened for the infections.
>New York City Department of Investigations Commissioner Rose Gill O'Hearn
http://www.ajc.com/metro/content/metro/stories/0423meshbodyparts.html?imw=Y
>When body parts such as heart valves, skin, bone, tendons and cartilage are legally taken from corpses, FDA rules require permission from the donor or relatives.
http://www.ajc.com/metro/content/metro/stories/0423meshbodyparts.html?imw=Y
>Minneapolis-based distributor Medtronic Inc. reported that at least 8,000 pieces that came from BTS were implanted, and others are being recalled, according to documents filed January in a federal lawsuit in Ohio.
>The Food and Drug Administration is concerned those parts could be infected with the AIDS virus, syphilis and hepatitis, but has said the risk of infection is small.
http://www.cbc.ca/story/science/national/2006/01/26/tissue-recall060126.html

How would you feel if you were the patient who the CDC discovered DID get an infectious disease from LASIK the occured AFTER the CDC and the FDA knew about this problem and did nothing? On behalf of the National Vision Institute, I contacted USA Today about running an ad. It would be nice for the FDA and the CDC to respond. Why should it be necessary to spend this kind of money on an ad just to get a response?

For every LASIK surgery as shown in Exhibit C,, every patient MUST have new microkeratome components (e.g., blades and cannulas). Reusing microkeratome components that come into contact with blood or the cornea on multiple patients is not within the practice of medicine for patients in the United States let alone within the standard of care for any Medical Doctor (for any medical procedure including LASIK). There is NO patient benefit for reuse and there is a very high risk of harm to the patient.

As shown in Exhibit C, Based on peer reviewed publications and other information already submitted to the FDA and the CDC as well as my review of the risks associated with reusing microkeratome blades or cannulas on multiple patients (especially without proper sterilization), this practice can spread infectious diseases (e.g., DLK, HIV, hepatitis, CJD, etc.) as well as corneal infections (a complication that does lead to loss of eye and blindness). Proper sterilization of the microkeratome blades with regard to CJD prions is not practical and the blades do come into contact with the eye and blood (which are considered highly infectious tissue). The microkeratome then inserts the tissue into the eye of any other patients it comes into contact with.

In addition, microkeratome blades get duller every time they are reused which causes irregular flaps made in the cornea, less smooth flaps, epithelial ingrowth, keratitis, and other serious problems. In general, the reuse or reprocessing of single use devices on multiple patients is a serious concern (see http://reform.house.gov/UploadedFiles/121605%20FDA%20Medical%20Device%20Letters.pdf).

Reuse also appears to be an off-label use or even violation of the FDA approval. Worse yet, the patients are exposed to the contaminated blades without resterilization. I think patients should be properly educated and informed prior to having LASIK surgery.

In light of present day Medical ethics, patients should be given true informed consent by a licensed medical professional (e.g., the M.D. Ophthalmologist surgeon explaining the true risks to physical and mental health). Unlicensed sales people who may be dressed to look as if they are medical professionals (e.g., wearing white lab coats) should not be allowed to explain things as their information may be incorrect and they may mislead patients.

Reusing a microkeratome blade used on another patient is not prudent and far too risky for patients. No patient should be subjected to a reused medical device that is labeled single use, and disposable even if the patient has informed consent. Reusing blades without patient informed consent violates many medical ethical principles including HHS IRB guidelines (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm), The Declaration of Helsinki "It is the mission of the physician to safeguard the health of the people" (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j6), the Belmont Report "Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. " (see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) and the THE NUREMBERG CODE "The voluntary consent of the human subject is absolutely essential." "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5).

Apparently, two Doctors in CA admitted to reusing a single blade on multiple patients and were placed on probation by the medical board, and I believe the penalty should be higher than this decision.

"LaserVue reused microkeratome blades among patients rather than sterilizing or replacing them. Former patients may have been exposed to infectious diseases such as HIV or Hepatitis. "
"Class Action o/b/o 2,700 former LaserVue patients. In a settlement to an investigation brought by Medical Board of California (MBC), defendants admitted that their protocol was to rinse and reuse a blade on up to 4 eyes. MBC concluded that defendants departed from standard of care and placed them on probation."
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http://www.lasikinfocenter.net/Webpages/Ongoing%20Litigation%20Against%20RS%20Webpage.htm.)

Some Doctors have even admitted to reusing blades on multiple patients without any sterilization at all.

Who would knowingly consent to a reused blade being used on them without any sterilization at all? These Doctors are also fully aware that the FDA may Not do anything to stop these highly risky practices because the FDA does Not regulate the practice of medicine or (in some cases) the use of the devices used to perform LASIK.

For every LASIK surgery, every patient MUST have new microkeratome components (e.g., blades and cannulas). Reusing microkeratome components that come into contact with blood or the cornea on multiple patients is not within the practice of medicine for patients in the United States let alone within the standard of care for any Medical Doctor (for any medical procedure including LASIK). There is NO patient benefit for reuse and there is a very high risk of harm to the patient.

Based on my review of the risks associated with reusing microkeratome blades or cannulas on multiple patients (especially without proper sterilization), this practice can spread infectious diseases (e.g., DLK, HIV, hepatitis, CJD, etc.) as well as corneal infections (a complication that does lead to loss of eye and blindness). Proper sterilization of the microkeratome blades with regard to CJD prions is not practical and the blades do come into contact with the eye and blood (which are considered highly infectious tissue). The microkeratome then inserts the tissue into the eye of any other patients it comes into contact with.

In addition, microkeratome blades get duller every time they are reused which causes irregular flaps made in the cornea, less smooth flaps, epithelial ingrowth, keratitis, and other serious problems. In general, the reuse or reprocessing of single use devices on multiple patients is a serious concern (see http://reform.house.gov/UploadedFiles/121605%20FDA%20Medical%20Device%20Letters.pdf).

Reuse also appears to be an off-label use or even violation of the FDA approval. Worse yet, the patients are exposed to the contaminated blades without resterilization. I think patients should be properly educated and informed prior to having LASIK surgery.

In light of present day Medical ethics, patients should be given true informed consent by a licensed medical professional (e.g., the M.D. Ophthalmologist surgeon explaining the true risks to physical and mental health). Unlicensed sales people who may be dressed to look as if they are medical professionals (e.g., wearing white lab coats) should not be allowed to explain things as their information may be incorrect and they may mislead patients.

Reusing a microkeratome blade used on another patient is not prudent and far too risky for patients, against public policy and contrary to the public welfare (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm). No patient should be subjected to a reused medical device that is labeled single use, and disposable even if the patient has informed consent. Reusing blades without patient informed consent violates many medical ethical principles including HHS IRB guidelines (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm), The Declaration of Helsinki "It is the mission of the physician to safeguard the health of the people" (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j6), the Belmont Report "Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. " (see http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm) and the THE NUREMBERG CODE "The voluntary consent of the human subject is absolutely essential." "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury." (see http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5).

Apparently, two Doctors in CA admitted to reusing a single blade on multiple patients and were placed on probation by the medical board, and I believe the penalty should be higher than this decision.

"LaserVue reused microkeratome blades among patients rather than sterilizing or replacing them. Former patients may have been exposed to infectious diseases such as HIV or Hepatitis. "
"Class Action o/b/o 2,700 former LaserVue patients. In a settlement to an investigation brought by Medical Board of California (MBC), defendants admitted that their protocol was to rinse and reuse a blade on up to 4 eyes. MBC concluded that defendants departed from standard of care and placed them on probation."
(see
http://www.lasikinfocenter.net/Webpages/Ongoing%20Litigation%20Against%20RS%20Webpage.htm.)

The Doctors did Not properly follow or train others to follow the FDA approved labeling for these FDA regulated medical devices. Without their knowledge or adequately informed consent, patients have received "off-label" treatments that were outside the protocols used for the clinical trials. The risks of any "off-label" use are totally unknown, More risky, and are Not studied adequately, but patients were falsely told it was approved by the FDA as "safe".

Informed consent is also lacking as FDA "approval" implies the safest possible treatment available at the time (that was approved by the FDA as "safe"). An "off-label" reuse of these devices is Not approved by the FDA and is Not as safe as a "on-label" use following the methods used in the clinical trials. They did Not follow the manufacturer or FDA labeling of the microkeratomes (a class I device) that indicates or should indicate that the blades or canulas are disposable, single-use devices (to be used on one eye and thrown away).

"DR. BULLIMORE: You use one. I'm sort of naive to this. Is there any sort of cleaning or scrubbing that needs to be done between the procedures, or you just strap it off one and onto the other?

DR. THOMPSON: That's correct, the latter. We don't do anything to the microkeratome in-between eyes." http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3315t2.pdf

Per Dr. Meyer who was trained at Emory, Emory Doctors have not set any standard for reuse of microkeratome blades on multiple patients. Even if reused on a single patient's second eye there is still unnecessary risk involved. Every time a blade is reused, it becomes more dull (increasing the risks of an already too risky surgery- see http://www.fda.gov/cdrh/LASIK/risks.htm) and can spread cornea particles and metal fragments as well as bacteria, fungus, infectious diseases and corneal infections (a complication that does lead to loss of eye and blindness). If patients were properly informed, I doubt many patients would consent to reused blades. In fact, some Doctors recommend offering to have patients pay an extra fee for a new blade on each eye, but they do Not go so far as to make this prudent standard the standard of care for all LASIK.

Will you use a different microkeratome blade (LASIK only) for each eye?

The answer may be yes, but many surgeons use one blade for both patient's eyes. You may request a new blade for each eye, but don't be surprised if the surgeon asks you to pay a little more for the extra blade.
http://www.usaeyes.org/faq/tough_questions.htm

In fact, Dr. Waring has been a paying member of the usaeyes (CRSQA) nonprofit organization. In my opinion, these reflect problems with inadequately specifying a prudent standard of care (knowingly). Many eye surgeries have been done with reused medical devices that are labeled single use, and disposable (patients blood and cornea tissue were shared between patients- which has a known risk of spreading HIV, CJD, and other infectious diseases). I believe the FDA and the CDC have opened investigations into these unacceptably risky practices involving LASIK. However, the FDA may Not do anything at all because they rely on the research that was submitted to them and the statements of these same Medical Doctors. The FDA's jurisdiction may be limited to regulation of the medical devices and they do Not regulate or act on behalf of consumers, or regulate either the Doctor, the practice of medicine, or the outpatient centers that provide the lasers and microkeratome equipment used on human patients (they DID set up a working group to address these issues). The CDC may Not do anything at all because their jurisdiction is deferred to the FDA because the FDA regulates the medical devices.

Other Doctors believe this is Not a prudent practice, and that is should stop.
>Dr. Will says LASIK surgeons tend to re-use disposable canulas but he notes that they are running the risk of inducing diffuse lamellar keratitis (DLK) if they sterilize disposable canulas using steam and then re-use them on additional patients.
"If you intend to re-use a disposable canula, you should use a dry heat sterilizer, but as a safety issue I discourage the re-use of any disposables," advises Dr. Will.
Reusable or Disposable Instruments?
Newer surgical techniques can dictate the choice.
BY JERRY HELZNER, SENIOR EDITOR
http://www.ophmanagement.com/article.aspx?article=86444

Is there NO limit to how much risk they're willing to accept? How many patients can a blade be reused on? How many patients was each blade used on in the clinical trials?

"Most respondents (78.7%) changed the microkeratome blade between patients while 49% in Europe and 36.4% in Oceania preferred to change the microkeratome blade between eyes. These preferences were similar to those in the 2003 survey. The microkeratome blade was changed after 2 or more patients by 11 .l% of Asian respondents and 55.0% of Latin American respondents, which was similar to the pattern in the 2003 survey (17.5% and 50.0%, respectively).

Surgical Technique. Ninety-seven percent of respondents would treat a pupil larger than the ablated area in patients with low myopia (<-6.0 diopters [Dl), and 70.1% would treat a pupil larger than the ablated area in patients with high myopia (> -6.0 D).
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15721716&query_hl=1
J Cataract Refract Surg. 2005 Jan;31(1):221-33.
Refractive Surgery Survey 2004.

Sandoval HP, de Castro LE, Vroman DT, Solomon KD.

Under GA law (based on case precedents), the standard of care is determined by whatever Doctors want to do, Not by what medical Doctors consider to be prudent. Thus, in GA Doctors can do whatever they want to patients and take whatever risks they want with patients lives as long as other Doctors say they are willing to do the same thing. The courts need to change, but the issues I'm raising here regard both the legality AND the ethics. Even if it's legal- if it's unethical then every moral person has a duty and an obligation to MAKE IT STOP NOW!

Emory Doctors have stated:
"The microkeratome existed before 1976 so the FDA immediately approved it. As a result, the regulation of microkeratome use is negligible if at all." (see "The History and Controversial Future of Refractive Surgery", 1999?, by Michael J. Ward who works at Emory; http://www.cse.emory.edu/sciencenet/undergrad/SURE/Articles/1999_art_ward.html).

Knowingly exposing patients to an increased risk of CJD, hepatitis, other infectious disease, bacteria, blepharitis, Keratitis (Diffuse Lamellar Keratitis, blepharitis, Epithelial Keratitis, etc.)... by Not sterilizing the microkeratome blades or canulas is unethical. Knowingly creating a standard of care during training of the "Emory technique" that is below the prudent standard of care for a medical Doctor or below the standard techniques actually used for the clinical trials is unethical. For instance, Dr. Thompson admitted to reusing the blades (and canulas) and Not sterilizing the microkeratome blades or canulas at all ("We don't do anything to the microkeratome in-between eyes.").

With regard to informed consent issues, I believe it is confusing and improper to charge the same price for each eye and for one eye the patient gets a reused blade and the other eye gets a new blade. Adequate informed consent would involve the patient deciding whether or Not to pay for a new blade even if it is determined to involve the same level of risk statistically (averages do Not necessarily apply to each individual and patients would need informed consent to decide for themselves to take on an increased risk whether or not it is prudent). How can the standard of care be to advertise quality results with the same price per eye, but to offer a lower quality on the second eye (vs. the first eye) by reusing a now old blade and canula?

Other Ophthalmologists agree that at least patients should be informed of the risk for reusing blades and/or canulas (single-use disposable FDA regulated medical devices)! Dr. Huang is an Ophthalmologist who was on the FDA's Ophthalmic devices panel.
"----- Original Message -----
From: Andrew Huang
To: 'Michael Patterson'
Sent: Wednesday, December 14, 2005 5:17 PM
Subject: RE: Request for beneficence regarding a public health threat and epidemic.

Dear Dr. Patterson: In general, I agree with you that the microkeratome blades should not be reused (without resterilization). In 1990's, many courtiers outside US were reusing blades for LASIK procedures and many cases of microbial keratitis (esp.. atypical mycobacterial keratitis and some are bilateral infections). I have witnessed some surgeons in South America using the same blade for

up to 12 eyes. However, there are two issues, one being reuse of the blade and the other being resterilization. In general, most of the disposable instruments or blades are approved for one-time use and reuse certainly is an off-label use or even violation of the FDA approval. Worse yet, the patients are exposed to the contaminated blades without resterilization.Nonetheless, Its is difficult to reinforcing the regulations to prohibit physicians from reusing the blades or equipments as long as they are properly resterilized. Many surgeons are reusing non-disposable equipments such as diamond blades, but these non-disposables are all resterilized before reuse. I think the patients should be properly educated and informed to choose surgeons for their refractive surgeries. Sincerely, Andrew Huang"

Note that LASIK complications are More likely to occur if a microkeratome (e.g., the blade or canula) is reused (on multiple eyes or multiple patients). Dr. Huang says: "Reuse certainly is an off-label use or even violation of the FDA approval. "

Shockingly, 21% of LASIK surgeons have publicly admitted that they reuse microkeratome blades and it's unlikely they are sterilizing them properly to protect against infectious diseases (see J Cataract Refract Surg. 2005 Jan;31(1):221-33; http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15721716&query_hl=1)

Multiple Doctors have emphatically told me that reusing blades on multiple patients is outside the standard of care, indefensible, etc. Although thousands of patients may continue to be injured by these practices in the future, if it's outside the jurisdiction of regulatory authorities (the FDA, CDC, local govt, etc.) then NOTHING will stop it despite the obvious serious threat to the nations public health (LASIK has been performed on over 8 million US citizens already).

One practitioner emailed the petitioner as follows:
"I do not think that a standard of care has been established for this issue. I use one blade for two eyes of one patient. "

"Canulas are not sterilized between two eyes of the same patient. Standard of care does not mandate sterilization of canulas or keratome blades between two eyes of the same patient."

"Doyle Stulting, George Waring, Keith Thompson, David Palay and Lou Wilson were the cornea faculty at Emory during my fellowship."

These practices are unacceptably tolerant of an unduly high risk level no matter how many Doctors have done it. If the canulas and/or blades are to be used once and thrown out, then Not doing so is unacceptable.

If there's no standard of care, and if the labeling is (or should be) that the medical devices are single use, disposable devices (to be used once and thrown out due to the risk of spreading CJD prions which requires highly specialized sterilization techniques) then this is NOT an ethical practice of medicine (in my opinion).

Dr. Waring also stated (in 1995?) that "we proceed with active teaching of hundreds or thousands of ophthalmologists to use a technique that we are simultaneously figuring out how to do—including the identification of complications and statistical outcomes."
And that it is "safer for patients and more rational for the profession to proceed in a graduated manner, refining the techniques and improving the results on smaller numbers of patients (or in the laboratory), and saving our mass education for the time when we have worked the bugs out of the technique and have acquired reasonably quantitative descriptions of safety and efficacy?"

From his own statements, Dr. Waring is well aware of the consequences of poor, inadequate training of other Doctors, but it seems he and his colleagues did it anyway. And the damage continues because these Doctors have NEVER BEEN PROPERLY retrained!

Dr. Waring promised the FDA that other Doctors would be properly trained. "The steps that I just outlined for you would be implemented at any site prior to their being able to use the Emory System".
"DR. WARING: Our efforts to train surgeons in the Emory LASIK technique go along the lines that we had in our initial PMA. We have outlined our 10-step training program there. It's not categorically different from the way we do skills transfer in any other part of ophthalmology. "
"DR. WARING: This is George Waring. For people to use the Emory System, they would have to be trained in the outline that I've told you. I myself might not train all of those surgeons, but we would provide a skilled surgeon to assist with that training, and the steps that I just outlined for you would be implemented at any site prior to their being able to use the Emory System."
http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3315t2.rtf

LASIK's FDA approval will allow Emory doctors to train other surgeons in Atlanta and elsewhere to use the procedure, Thompson said. Doctors from Birmingham, Ala., and Greenville, S.C., already have made plans to perform LASIK at the vision correction center, Thompson said.

Earlier this month, an FDA advisory panel recommended approval of LASIK, a laser eye surgery that has a rapid recovery time, causes minimal discomfort and allows for further vision adjustments when needed in the future, an advantage over techniques previously approved by the FDA, LASIK researchers said.

http://www.bizjournals.com/atlanta/stories/1998/06/29/newscolumn5.html

Apparently, practitioners were Not properly trained to wait before reapplying the microkeratome after an incomplete LASIK flap and to Not attempt another flap right away as serious complications can occur. It is a further deviation not to inform the patient of this complication at the time of surgery and not to document this complication in the records, but two practitioners were unaware or do Not follow this practice with these regulated devices.

It is unethical to take unnecessary risks, or conduct experiments on human beings without a proper basis to believe it is in the patients' best interests. It is unethical to Not Follow or avoid IRB and/or research guidelines established by medical review boards, medical Doctors, and/or the government (e.g., the FDA, CDC, etc) to protect research subjects.

These ethics extend to U.S. Doctors regardless of whether the research is conducted in the U.S. or overseas. Numerous "deviations" from Title 21 Code of Federal Regulations have been noted. For instance, see http://www.fda.gov/foi/warning_letters/m2875n.pdf

The FDA has chosen Not regulate "the practice of medicine" in any way. In practice that means the FDA has Not regulated Medical Doctors even though they are the users of these devices. Thus, effectively the FDA is merely placing a "approval" on these devices that it is possible to safely use them, but Not regulating that these devices are actually used safely Or in the way they are labeled to be used.

However, practice of medicine does not allow anyone, including medical doctors, to break Federal or State laws. Furthermore, any user of these Class I devices (whether licensed physician or not) who violates the labeling of these devices unnecessarily exposing patients to a non-Prudent degree of risk does not provide informed consent, and therefore, is not practicing medicine by definition. Thus, these practices are within the regulatory authority of the FDA.

As the CDC and the FDA is aware, sterilization guidelines are different for surgical components that come into contact with highly infectious tissue (blood and cornea), and most stringent when there's no prescreening of the tissue/patients for these infectious diseases. CJD sterilization techniques are even more stringent and require that the devices be disposed of which is Not only how the Hansatome microkeratomes are labeled, but also how they are licensed and sold to Doctors as well as patented for use. In many cases, the Operator Manual procedures (see Exhibit D, including sterilization and cleaning off of debris) are Not even followed by the users of these devices.

The old 510(k) sterilization method indicated in the
"Hansatome Microkeratome DRAFT 12-14-2000 Operator's Manual"
was to use alcohol.

The new sterilization method is to use EtO which is Not stringent enough and Not all components were even sterilized this way according to 510(K) #K010260 (dated 2001) Hansatome Microkeratome. This was a change to their last 510K #d K972808 (Hansatome Microkeratome cleared 10/24/1997) and K913697 (Automatic Corneal Shaper) which include the INNOVATOME (K973294/A- 10/3/97) and the Nidek (K990900- 9/24/99).

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p.12 "April 27, 2001 I left a messages for Mr. Kramsky and Mr. Gary Rauvola regarding EtO sterilization of the tubing and blades. I finally was able to reach Mr. Kramsky, he stated that the elimination of EtO sterilization only referred to the components for the tray and that the blades and tubing will continue to be EtO sterilized."

EtO uses low heat instead of autoclaving.
http://www.devicelink.com/mddi/archive/98/12/006.html
"Hansatome Microkeratome DRAFT 12-14-2000 Operator's Manual"
"Bausch & Lomb Surgical is the owner of U.S. Patent No. 4,840,175. "
"A license for single-use only procedure under U.S. Patent No. 4,840,175 to perform the patented procedure claimed in said patent may be obtained from Bausch & Lomb Surgical with the purchase

of each single-use Bausch & Lomb Surgical AccuGlide disposable blade. U.S. Patent Nos. 5,624,456; 5,772,675; 6,007,553; 6,042,594; and 6,051,009. Date effective November 2000". "Caution: Federal Law (U.S.A.) restricts this device to sale, by or on the order of, a physician".

p.17 "26. Warning It is important to follow proper surgical procedure and carefully drape the eyelids and lashes. Failure to do so could result in possible serious permanent patient injury." "27. Warning If vacuum seal to the patient's eye is lost during a cut, never attempt to regain suction and continue, or to immediately repeat the procedure. Doing so could result in serious permanent patient injury."
"31.... NOTE: Any tissue lodged in the Hansatome microkeratome head should be removed immediately. This will prevent the tissue from hardening or becoming lodged in the cavity of the Hansatome microkeratome head."
"34. Warning The Hansatome microkeratome must be cleaned, disinfected and/or sterilized according to the instructions provided in this manual. Failure to properly clean, disinfect, and sterilize equipment could result in possible serious permanent patient injury."
"36. Warning Any delay in cleaning can allow residual debris from the procedure to adhere to the Hansatome microkeratome. Such debris could clog the Hansatome microkeratome and during sterilization, could harden and become permanently lodged. Debris allowed to build up on the Hansatome microkeratome components could affect the performance of the system resulting in system malfunction and possible permenant patient injury."
"43. Warning Do not sterilize the Hansatome microkeratome head iwth the AccuGlide blade installed. This could result in the blade becoming wedged in the head or result in damage to the head. Damage of this nature could result in possible serious permanent patient injury."
p.3-1 indicates using Alcohol for cleaning which apparently changed with the new 510K dated 2001.

The blade manufacturer changed (i'm guessing for quality reasons)- they blanked out the old one in one place, but January 26,2001 Re: Traditional 510(k) Premarket Notification- Hansatome Microkeratome shows "the Hansatome Microkeratome was previously manufactured at Hansa Research and Development, Inc. at 7790 N. W. 55th Street, Miami, FL, 33166 (also see the bottom of this email- letter from an insider at the Miami plant regarding manufacturing quality problems).

The new one in the same above document is Bausch & Lomb at 3365 Tree Court Industrial Blvd, St. Louis, MO, 63122, but another document says it is American Safety Razor and sterilizer is Griffith Micro Science.
xxxx
So here's the problem- the Doctors did Not properly sterilize or follow the Operator's manual regarding reuse of blades.
1. Dr. Thompson admits to violating the labeling and Federal law (see below for the labeling) by reusing the blades without sterilization.
"DR. BULLIMORE: You use one. I'm sort of naive to this. Is there any sort of cleaning or scrubbing that needs to be done between the procedures, or you just strap it off one and onto the other?

DR. THOMPSON: That's correct, the latter. We don't do anything to the microkeratome in-between eyes." http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3315t2.pdf

2. Dr. Meyer trained by Dr. Thompson and others admits the same.

Per Dr. Meyer who was trained at Emory, Emory Doctors have not set any standard for reuse of microkeratome blades on multiple patients. Even if reused on a single patient's second eye there is still unnecessary risk involved. Every time a blade is reused, it becomes more dull (increasing the risks of an already too risky surgery- see http://www.fda.gov/cdrh/LASIK/risks.htm) and can spread cornea particles and metal fragments as well as bacteria, fungus, infectious diseases and corneal infections (a complication that does lead to loss of eye and blindness). If patients were properly informed, I doubt many patients would consent to reused blades. In fact, some Doctors recommend offering to have patients pay an extra fee for a new blade on each eye, but they do Not go so far as to make this prudent standard the standard of care for all LASIK.

3. As a member of CRSQA, Dr. Waring (another Emory Doctor) also knows the microkeratome users are reusing the blades.

Will you use a different microkeratome blade (LASIK only) for each eye?
The answer may be yes, but many surgeons use one blade for both patient's eyes. You may request a new blade for each eye, but don't be surprised if the surgeon asks you to pay a little more for the extra blade.
http://www.usaeyes.org/faq/tough_questions.htm

CHECKLIST OF COMPLIANCE WITH ESSENTIAL REQUIREMENTS OF MEDICAL DEVICES DIRECTIVE
Bausch & Lomb Surgical 10 August 2000
1. General Requirements IEC 601-1 & IEC 601-1-4 IEC 601-1-2 EN1441
1. The device must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or , where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighted against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. Essential Requirements
2. ... In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:
-eliminate or reduce risks as far as possible (inherently safe design and construction)
-where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated
-inform users of the residual risks due to any shortcomings of the protection methods adopted

3. ...
4. "the characteristics and performances referred to in Sections 1, 2, and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the

manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use."
NOTE: "normal conditions of use" above

xxxx
"Subj: Amendment to Provide Information Per Keratome Checklist"
"Other than the blade blank supplier, the only other changes made to the Hansatome since the clearance of K972808, which Bausch & Lomb concluded do not necessitate a new 510(k), are revisions made to the Operator's Manual as noted in Section 7 of K010260. These changes involved either clarification or updating of some of the user instructions, including the sterilization, disinfection, or cleaning of the device and its acessories, as noted in Section 13 of K010260. These changes were made as a result of the experience gained with this device over the years that it has been in use since clearance of K972808, but otherwise do not affect the indications for use or safety and effectiveness of the device.""

p.4 "the risks are low and well known based on clinical experience. There are no new risks introduced by the specific indication for use."
p.10 "6. Hazards Analysis:" "provide a table showing hazard, generic causes, and the controls applied to mitigate or obviate the following hazards."
"a. loss of power"
"b. loss of vacuum, or incorrect vacuum;"
"c. incorrect assembly"
"d. free flap: is there a mechanical stop, or is distance traveled under software control? could insufficient vacuum cause a free flap?"
"e. Penetration and wrong cut depth; wil incorrect assembly cause a penetrating cut or wrong depth of cut; will incorrect user operation affect these?"
"f. irregular cut: bad blade, poor user operation, too fast cutting?"
"g. poor centration: visible centration marks; incorrect vacuum ring positioning; user training?"
"h. excessive IOP: warning bells and whistles of excessive vacuum; vacuum control failure?"
"i. incomplete cut: loss of power, user lifts keratome head too soon; mechanical stop incorrectly positioned"

p.11 "The labeling should include Device manufacturer name and address and the following Prescription device caution (CFR 801.109(b)(1): "Caution: Federal law restricts this device to sale by or on the order of a Physician or Licensed Practitioner"

p.12 "April 27, 2001 I left a messages for Mr. Kramsky and Mr. Gary Rauvola regarding EtO sterilization of the tubing and blades. I finally was able to reach Mr. Kramsky, he stated that the elimination of EtO sterilization only referred to the components for the tray and that the blades and tubing will continue to be EtO sterilized."

page 11 - Keratome Guidance
Device Specific info.

	Adequate	
Accuracy/Variability	yes	pg# 082-083

Side-by-side comparison with predicate(s) per Section V.B. with Explanation of differences
Disposable/reusable/sterile yes pg #024-025

Biocompatibility
Disposable, Single Use (Validated) yes pg #245
Reusable, User Clean & Sterilize (Validated) yes pg #035, 103
Proposed labels, labeling, and advertisements (if available) which describe the device, its intended use, and directions for use yes pg #007-072

xxxx
Hazard Analysis Report for Hansatome System
October 1997 chiron Vision Corporation Clarement, CA
ALL BLANK PAGES (redacted out)

Failure Modes and Effects analysis for the Hansatome System
October 1997 chiron Vision Corporation Clarement, CA
ALL BLANK PAGES (redacted out)

xxxx
http://72.14.207.104/search?q=cache:HUjzAkL9XPsJ:www.lasikdisaster.com/bausch_and_lomb.htm+brent+letter+hansatome+quality+microkeratome&hl=en&gl=us&ct=clnk&cd=1
From: "steve" <____@____.com>
To: <brent@lasikcourt.com>
Sent: Monday, July 22, 2002 3:48 PM
Subject: Lasik, B&L & TLC my thoughts

I found your site very interesting. For 14 years I was involved in the development of the MicroKeratome that were marketed by Bausch & Lomb. I had a great deal of experience with TLC when I worked as the service department supervisor for Bausch & Lomb. 13 years ago I started worked on the prototypes for the ACS MicroKeratome and 3 years ago I was there when Bausch & Lomb bought Hansa Research & Development Corporation, the true developer.

I was the production supervisor in charge of manufacturing parts up until May of 2002. I actually had a hand in the development of the ACS and Hansatome. I am probably one of the top 5 individuals with the most knowledge about its problems and shortcomings. I was discarded during restructuring in May as the local plant began a series of cutbacks.

About TLC? MicroKeratome returned for service from TLC were some of the worst kept medical devices imaginable. Dirty and beat up by a group of doctors that share equipment like you rent bowling shoes. The problem with a group of people sharing the use of delicate equipment is that nobody cares about its upkeep. Units were treated like tools, wrenches and screwdrivers, and tossed around like the toolbox in the trunk of your car. The people at TLC were the worst to deal with. Demanding quick fixes to destroyed equipment and the blame was always the equipment never the user.

Bausch & Lomb has now developed it's own more serious problems. In January of 2001 a new plant manager took over the facility here in Miami, Florida where the first MicroKeratome was built and where the Hansatome is produced.

From then till now that facility has undergone a series of cutbacks that effected quality and will be the end of the Hansatome project. That new manager had a personal falling-out with the previous manager and decided to replace the entire power structure of the facility to spite him. He has now done that by neutralizing 5 key people. Unfortunately for the project he has neutralized the supporting knowledge base. The people building Hansatomes were once surgical instrument makers and machinist. Now the device is built by housewives and teenagers in an assembly line production. You can figure out what happened to the quality.

Anyway this last year the production has gone down hill fast and here is a copy of my letter to the FDA in June, I fear they will not take is seriously. This facility needs attention.

Bausch & Lomb Miami

The Bausch & Lomb facility at 7790 NW 55th St. in Miami Florida is engaged in the production of the surgical instrument known as the Hansatome Micro Keratome. In this last year the quality of the product has deteriorated to a dangerous level. This effort to reduce cost, cut corners and implement assembly line type manufacturing has now out weighed the need to maintain quality, in this product that actually cuts the human eye. Actual patient injuries have occurred as a result of this effort to cut cost while boosting output. The Repair Dept. covers those tracks. Micro Rings and Micro Heads are being produced in volume without the necessary Quality Controls. The current Quality Manager is in the process of being replaced for voicing his concerns.

The rush to bring the new Z-Heads, Micro Suction Rings and the new 20MM Micro Suction Rings into production, was driven by Marketing and should have required a new 510(k). All other factors take a back seat to that need to hit the market with a new generation device. We are engaged in developing the new prototypes and at the same moment the plant manager is cutting resources. Reducing wages for supervisors and reduced hours for employees.

Reduced availability of tools and equipment. Cutting corners. Gages, measuring tools and cutting tools are in short supply. SPC is non existent and created after the fact as needed.

The design measurements and calculations for the calibration of the Z-Heads are flawed. The prototypes used in the clinical tests were re labeled several times since they did not produce the expected results. They did not cut the correct thickness as predicted by engineering so the numbers on the heads were changed several times. The design was never reevaluated and under pressure from the plant manager the project pushed forward to production and product release in order to meet his timeline. The actual heads used in the clinical evaluation do not match the manufacturing drawings for the release.

Many small changes have gone undocumented in the effort to push forward.

This device is claimed to cause less compression on the flap when in fact it increases the compression of the entire eye and it is much greater pressure than the ACS unit. Several design changes have inched the Micro Keratome head closer to the eye increasing the IOP. So many Micro Heads were produced so fast that the documentation could not keep up causing heads with similar labels in inventory to have differing dimensions. This creates confusion when calibrating and installing these heads in new and service units.

The manufacturing process for Micro Suction rings and the new 20MM Ring has never been perfected even though production of the rings has increased. The development suffered from cutbacks. The FAIR's on the 20mm rings were done long after the rings were in clinical testing and were not done on the same rings used in the testing. On the Micro Suction rings, discrepancies in the measurements that control the exposure of the cornea above the ring have caused many Free Flaps as noted by the service department. Quality control in the manufacturing is lacking because of increased volume and cutbacks.

Many rings have varying dimensions. Defective rings are taken out of service or modified when found in service units.

There are massive across the board discrepancies in documentation of Prints, PCPs, SOPs and manufacturing procedures that are incorrect. Actual print dimensions are in error in many cases. This is made worse by cutbacks and restrictions in an effort to save money. GMP and ISO are the goals but the facility is in a state of disarray at this moment. The employees are working blind with an ever growing pressure by the manager to produce more volume in less time. When B&L bought this company 2 years ago documentation was minimal. Much of it was created immediately by a remote engineering department in many cases by people with no knowledge of the device. It was incomplete and flawed and in need of repair. In the last 2 1/2 years only small progress has been made in correcting the documentation and in the last year that correction process has been all but abandon. Procedures for such things as Part Machining, Assemble, Heat Treating, Hardness Testing and Servicing are in need of attention. These documents are incomplete and not understood by the employees. This is due to lack of resources, cutbacks in financing and personnel, lack of proper training and the unyielding pressure to produce more with less and to do it in less time.

Steve ____
X Production Supervisor
Bausch & Lomb Miami
Actions Requested of the FDA.

3. Action requested--What rule, order, or other administrative action does the petitioner want FDA to issue, amend or revoke?
The Petitioner is willing to work with the FDA and any other Federal agencies in assisting with further development of the implementation of any injury prevention efforts including, but not limited to the following actions.

3.1 ACTION 1. The Petitioner request a moratorium on any further non-medically necessary elective eye surgeries other than for strict humanitarian purposes.

The severity, totality of the risks (and their likelihood) of actual injuries to the public that have occurred from the actual practice (including non-research centers) of non-medically necessary elective Refractive Eye Surgeries are a larger risk to the public health than identified in previous research and Prudent injury intervention strategies are Not feasible to adequately protect the Public from injury.

There is a precedent for this recommendation: "The Food and Drug Administration today called for a moratorium on the use of silicone gel breast implants until new information on their safety can be thoroughly reviewed by an independent advisory panel and the agency can make a final decision in light of the panel's review." (http://www.fda.gov//bbs/topics/NEWS/NEW00263.html).

ACTION 2. The Petitioner believe that the potential risks versus possible benefits assessment favor a moratorium and/or withdrawal of FDA approval for these devices.

There is a precedent for this recommendation: "The FDA brings together its General and Plastic Surgery Devices Panel to review all of the safety data from the manufacturers' PMA's. The purpose of the panel is to advise FDA as to what they could tell the public about the safety and effectiveness of the silicone breast implants based on the PMA's. The panel is composed of a broad range of experts, including representatives from the fields of plastic surgery, oncology, epidemiology, internal medicine, immunology, radiology, pathology, gynecology, toxicology, sociology, biomaterials and psychology, as well as industry and consumer groups. The panel hearing rejects the data from Dow Corning, Mentor, McGhan, and Bioplasty, concluding there is not sufficient data about the risks and benefits of the devices. The panel recommends the devices stay on the market temporarily and with limited access. The need for more safety data is stressed." (http://www.pbs.org/wgbh/pages/frontline/implants/cron.html)
Review each of these class I devices to assess whether the device is EITHER as safe or substantially equivalent to the legally marketed devices that were or are currently on the U.S. market that the manufacturers used for comparison purposes in their 510(k) submissions for their PMA approvals (http://www.fda.gov/cdrh/dsma/pmaman/front.html; http://www.fda.gov/cdrh/dsma/pmaman/Table%20of%20Contents.html#TopOfPage). As part of this surveillance process, the Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." Is reasonable based on the available evidence at this time. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). See Appendix B and C for further discussion and consideration of this action.

3.3 ACTION 3. Hold an Ophthalmologic advisory panel meeting to consider the research, medical ethics, and any surveillance data to decide whether there is now sufficient data on safety and effectiveness for these class I devices to continue to serve a public health need and whether they should continue to be approved by the FDA. At what point are the risks of certain types of procedures, equipment or procedures significantly higher such that they should banned?

3.4 ACTION 4. Oversee the entire life cycle of these devices--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals.
The Petitioner challenges you to review suggestive findings regularly to identify how some modifications to the potential "candidates" might be safer for the Public Health. Isn't the first priority to "first do no harm"?
For the Agency to oversee their entire life cycle--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals. Along with this after market surveillance process, the Petitioner also ask the FDA to reconsider whether the potential risks versus possible benefits assessment favor this action, whether SSED documents provide a reasonable assurance of safety and effectiveness for the device as labeled based on the nonclinical and clinical studies described in the PMA, and whether the SSED accurately summarizes both the positive and negative aspects of the scientific evidence as required for each PMA (http://www.fda.gov/cdrh/dsma/pmaman/sec03.html#P784_26552). The Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k), and whether all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted and was reasonable based on the available evidence at that time" (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807).

3.5 ACTION 5. Conduct a retrospective comprehensive study of the incidence and prevalence of injuries to track ALL the relevant risks. Gather and collect all surveillance and monitoring data to allow proper education and targeting of interventions. Could the Medical Device Surveillance Network, MedSuN program be used for this purpose? The United Sates Eye Injury Registry (USEIR; http://www.useironline.org/Index2.html), a federation of state eye registries, uses a standardized form to obtain voluntarily reported data on eye injuries.
Many public health safety issues have Not been adequately researched.

3.6 ACTION 6. If newer devices become available which have better safety records, then remove the approvals for the older devices. For instance, Intralase lasers have been shown to have a much better safety record (as much as 10 times fewer problems and less serious problems) than mechanical Microkeratome blades for making LASIK flaps. Simply remove the approvals for the older mechanical Microkeratome blades unless they can be shown to be as safe as the newer Intralase lasers.

3.7 ACTION 7. Develop a national agenda for the prevention of injuries from elective refractive eye surgery and implement it through coordination of federal efforts across a variety of private and public agencies including the Department of Health and Human Services. Uniform legislation should be required by law, enacted and enforced in every state to mandate specific minimal safety practices.

1. Standardized equipment preparation and cleaning procedures should be identified and addressed. For instance, other instruments used with these PMA devices could be evaluated to minimize

bacteria and other problems (that can cause DLK or the transmission of diseases between patients such as CJD).
2. Improper use of equipment or procedures, or product malfunctions must be reported to CDRH. The FDA must enforce penalties that require accurate reporting.
3. Other requirements to be determined by future research.

4. No known Environmental Impact

5. Certification

To the best of the Petitioner' knowledge, the petition includes the information relevant to the petition, favorable or not.

Michael Patterson 5/11/06

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