February 25, 2013
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

2013 FEB 26 A 10:29

Citizen Petition

The undersigned submits this petition under Section 510(k) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to amend its order K121326 dated January 25, 2013 in respect to Lantos Technologies (see attached).

A. Action requested

Petitioner Wess Eric Sharpe hereby petitions the Commissioner to reconsider his classification of Lantos Technologies' 3D Ear Scanner in Class I, for the reasons given in Section B below. In light of the evidence presented below, I request that the FDA classify the Lantos 3D Ear Scanner as a Class II device under product code ETY.

B. Statement of grounds

According to the Device Description in its 510(k) Summary, the Lantos 3D Ear Scanner "consists of a silicone conforming membrane, which when in use is filled with an absorbing medium..." This fluid-filled membrane—which is the critical part of topology measuring system—is not part of the Identification of a Class I, code ERA device. To the contrary, this feature is described as part of the Class II, code ETY device identification: "a device that is intended to change the air pressure in the external auditory canal...." Consequently, the Lantos 3D Ear Scanner should have been classified as a Class II, code ETY device.

There are safety concerns regarding the fluid-filled membrane that are not at all envisioned by the description of Class I, ERA code. As the membrane is filled with fluid, it forms a seal around the ear canal at some location and then exerts pressure in the ear canal between the device's membrane and the tympanic membrane. I have a great concern about the safety of the inflatable membrane in the ear canal. Depending on where the seal is first made, there is possibility for a significant amount of pressure—even rupturing pressure—to build up on the tympanic membrane. Testing to mitigate against this concern is not presented in the 510K summary. I respectfully request that the FDA reconsider whether the Lantos 3D Ear Scanner can be cleared without sufficient proof that it cannot rupture the tympanic membrane.

C. Environmental impact

None noted.

D. Economic impact

Not applicable.

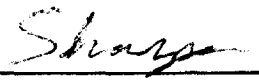
E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

2013-1449 PRC

FDA-2013-P-0235

Very truly yours,



Wess Eric Sharpe

2700 Paces Ferry Road
Unit 303
Atlanta, GA 30339-7902
404-909-2220

K121326

LANTOS TECHNOLOGIES
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Cambridge, MA 02142
+1.617.500.9800
www.lantostechnologies.com

6. 510K Summary

JAN 25 2013

Applicant:

Lantos Technologies
101 Main Street, Suite 1770
Cambridge, MA 02142, USA
Tel: 1-617-500-9800

Date Prepared: January 17, 2013

Contact: Lora Allemeier

Device Identification:

Trade Name – **Lantos 3D Ear Scanner**
Common Name – otoscope
Classification Name – otoscope (21 CFR 874.4770, Product Code ERA)
hearing aid, accessory (21 CFR 874.3300, Product Code ESD)

510(k) Numbers and Product Codes of equivalent devices:

Welch Allyn Video Otoscope (Skaneateles Falls, NY)

Welch Allyn Otoscope; K943916 – SE 08/25/1994

Code: ERA; 874.7440

Device Description

The device consists of a hand held scanner, a single patient use disposable with a silicone conforming membrane, which when in use is filled with an absorbing medium, and a laptop computer. The hand held scanner, when not in use, is placed in a docking stand.

The hand held scanner is tethered to the docking stand with a custom cable. The laptop computer is mounted on the docking stand. The hand held scanner contains LED illumination, optics, a camera, a motor to move the probe tip, and a motor-driven reservoir.

User Interface (UI) software screens are displayed on the laptop and the user interacts with the device via the laptop keyboard and touchpad, and control buttons on the hand held scanner, as guided by the UI screens. Image data from the patient is stored in the laptop, and may be transmitted by the user via a wireless connection. No patient identifiable data is stored in the Lantos device.

A single use disposable, which includes the conforming membrane, is placed over the hand held scanner probe tip, in a manner similar to placing an ear

speculum over the viewing tip of a conventional otoscope. The disposable includes a clear window over the probe tip. The probe can be used to inspect the ear canal, when inserted into the ear canal no closer than 4-5 mm from the tympanic membrane.

Additionally, the disposable can be filled with an absorbing medium so the membrane conforms to the ear, to enable the 3D scanning functionality of the device. After scanning is complete, the absorbing medium drains from the disposable so that the probe and disposable can be removed from the ear canal. The topographical measurement (scan) of the ear may be transmitted and may be used in the same manner as a desktop scan of a silicone earmold impression.

Indications for Use

The Lantos 3D Ear Scanner is intended for use by a trained hearing professional on patients 18 years of age and older presenting for inspection of the external ear canal.

The Lantos 3D Ear scanner:

- provides a magnified visual image for inspection of the external ear canal and tympanic membrane, and provides illumination of the ear canal for inspection and;
- includes an expanding membrane that can be inserted and conforms to the external ear canal when filled with an absorbing medium which enables the 3D scan and;
- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Intended Use Population

The Lantos 3D Ear Scanner is indicated for use by trained hearing professionals on patients 18 years of age and older presenting for inspection of the external ear canal.

Technological Characteristics

The Lantos 3D Ear Scanner is not a change or modification to the predicate device that could significantly affect safety or effectiveness. In other words, there is no change in the intended use (otoscope and hearing aid accessory), design (hand-held with illuminating LED probe tip covered by silicone cover), materials (polymers and silicone), and power source that could raise new issues of safety or effectiveness.

The Lantos 3D Ear Scanner followed ACGIH *American Conference of Governmental Industrial Hygienists Threshold Limit Values for chemical substances and physical agents and Biological Exposure Indices. 2011.* For both intended use and reasonably foreseeable misuse, the Scanner falls within ACGIH Threshold Limit Values for retinal thermal exposure within 10 seconds, blue light exposure within 10000 seconds, actinic ultraviolet radiation within 8 hours of operation and near UV exposure. In addition, the illumination subsystem was evaluated according to ANSI/IESNA *RP-27.3-2007 Recommended Practice for Photobiological Safety for Lamps-Risk Group Classification & Labeling* to provide a photobiological hazard evaluation (including blue light hazard exposure limits). This evaluation resulted in a "Risk Group 1" classification for the blue-violet LED. The exposure time limit for Risk Group 1 was 15 minutes of direct, continuous exposure to the scanner tip without the membrane attached. Package labeling includes a caution: "Do not stare at the scanner tip, or direct scanner tip toward patient's face, while illumination is active. Staring at scanner tip for more than 15 minutes with no membrane attached under fault conditions may exceed photobiological exposure. May be harmful to the eyes."

The output of the Lantos 3D Ear Scanner was validated using two known models (cylindrical and anatomical) with given values and obtaining multiple scans on each using multiple Scanner units. All scans were required to have a mean difference between the model and the scan consistent with manufacturer's requirements for fabrication of devices inserted in the ear.

Performance Standards

The Lantos 3D Ear Scanner meets the following Recognized Performance Standards:

- ISO 10993 Parts 1-13 as applicable

- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2 – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 14971: Medical devices—Application of risk management to medical devices

Conclusion

Based on the comparison of the technological characteristics (including the intended use) and verification tests of the Lantos 3D Ear Scanner, there are no significant new issues of safety and effectiveness that are raised when compared to the predicate device. The Lantos 3D Ear Scanner provides for inspection of the ear canal comparable to the predicate otoscope device and also allows for ear canal measurements, which may be used for the manufacture of hearing devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 25, 2013

Lantos Technologies
% Mr. John Greenbaum
Generic Devices Consulting, Inc.
20310 SW 48th Street
Southwest Ranches, FL 33332

Re: K121326
Trade/Device Name: Lantos 3D Ear Scanner
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA, ESD
Dated: December 18, 2012
Received: December 19, 2012

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121326

INDICATIONS FOR USE

510(k) Number (If Known): K121326

Device Name: Lantos 3D Ear Scanner

Indications for Use:

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- records and presents to the hearing professional in an image file a topology measurement of the external ear canal

Prescription Use__X__ AND/OR Over-the Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121326

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