DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

G.N.S neoLaser Ltd.
Mr. Gil Shapira
Chief Executive Officer
7 Ha'Eshel Str. 38900
Caesarea ISRAEL, P.O. Box 3203

December 8, 2015

Re: K152722
Trade/Device Name: neoV980 & neoV1470 Diode Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 15, 2015
Received: September 21, 2015

Dear Mr. Shapira:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152722

Device Name
neoV980 & neoV1470 Diode Lasers

Indications for Use *(Describe)*
The neoV980 & neoV1470 Diode Lasers, (and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation, and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Title: neoV980 & neoV1470 Diode Lasers

Submitter: G.N.S neoLaser Ltd.
Ha'Eshel St. 7, 38900, Caesarea ISRAEL, PO Box 3203

Contact: Gil Shapira, CEO
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Date Prepared: July 15, 2015

Device Trade Name: neoV980 & neoV1470 Diode Lasers

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered laser
GEX
21 CFR 878.4810

Predicate Devices: Quanta Diode Laser Family (K100558), Ceralas 1470nm Diode Laser (K112253) and Ceralas 980nm Diode Laser (K112324)

Device Description: neoV980 & neoV1470, members of the neoV Diode Lasers family, cleared under K133006, are medical grade, solid-state, infrared Diode lasers, designed to deliver continuous or pulsed, infrared laser energy at wavelengths of 980nm and 1470nm respectively, with power level ranging from 10 to 20 Watts respectively. The lasers are controlled via a high-resolution color touch screen. The touch screen display includes a user interface allowing selection of continuous, repeat pulse, or single pulse modes of operation as well as repetition rates, aiming beam settings, password key protection, and standby/ready mode selection. The units have an emergency shut off button on

the front of the unit.

The Laser System: The laser system consists of an optical block which contains the laser diode, mirrors, lens, and aiming beam diode, an air cooling system, and electronics which include the color touch screen control panel. The unit utilizes an external low voltage power supply, as well as an external wired foot switch for laser activation.

The Delivery System: The delivery system consists of either sterile fibers (not provided with the system) or non-sterile fibers and hand pieces.
Safety goggles, non sterile fibers, handpieces and a safety sign are provided with the unit.

Intended Use: The neoV980 & neoV1470 Diode lasers are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein
reflux.

Substantial Equivalence: The neoV980 & neoV1470 Diode Lasers share the same intended use, technical and performance characteristics of the predicate devices Quanta System QUANTA Diode Laser Family (K100558), the Ceralas 1470nm Diode Laser (K112253) and the Ceralas 980nm Diode Laser (K112324).

Conclusion: From a design and clinical perspective, the predicates and subject laser devices, have the same technological characteristics and share the same intended use. Accordingly, the safety and effectiveness of the neoV980 & neoV1470, is based upon a determination of the substantial equivalence to the predicate devices.

Non clinical Performance Data: The neoV Diode Laser family including neoV980 & neoV1470 has been tested for compliance to IEC 60601-2-22: 2007 (Third Edition), Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment, IEC 60601-1: 2005 (Third Edition) Medical electrical equipment Part 1: General requirements for basic safety and essential performance and tested for compliance with all functional requirements, IEC 60825-1:2007 Safety of Laser Products – Part 1: Equipment classification, requirements and user's guide, EN 60601-1-2: 2007, Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests.

Clinical Performance Data: None