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

April 17, 2014

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

Re: K133006
Trade/Device Name: neo Diode Laser Family
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: March 16, 2014
Received: March 25, 2014

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 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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 on last page.

510(k) Number *(if known)*
K133006

Device Name
neoV Diode Laser Family

Indications for Use *(Describe)*
The neoV810 diode laser is 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 specialist 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.
The neoV980 diode laser is 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 specialist 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.
The neoV1064 diode laser is 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 specialist 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.
The neoV1470 diode laser is 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 specialist 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.04.16 11:46:28 -04'00'

For BSA