



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

December 22, 2015

Sheaumann Laser, Inc  
Katina Sousa  
Quality Systems Administrator  
45 Bartlett Street  
Marlborough, Massachusetts 01752

Re: K150664

Trade/Device Name: Neolas

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: November 12, 2015

Received: November 13, 2015

Dear Katina Sousa:

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" (21 CFR 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,

**Binita S. Ashar -S**

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

## Indications for Use

510(k) Number (if known)

Device Name

NeoLas

Indications for Use (Describe)

The NeoLas Er:YAG laser, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

In dentistry for:

Endodontic Surgery (Root Amputation) Indications:

- Root end preparation for retrofill amalgam or composite
- Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex.

NOTE: Any tissue growth (i.e. cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation

Laser Periodontal Procedures:

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

The NeoLas 810nm Soft Tissue laser and its accessories are intended for use on adult and pediatric patients in dentistry, dermatology and other surgical areas in the following procedures:

Soft Tissue Indications including Pulpal Tissues\*

Incision, excision, vaporization, ablation and coagulation or oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation—incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation—incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation

- Implant recovery
- Incision and drainage of abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex
- Root canal debridement and cleaning
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcer of the oral mucosa
- Vestibuloplasty

NOTE: Any tissue growth (i.e. cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation

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.**

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# SHEAUMANN

## **510(k) Summary**

### **510(k) Owner:**

Sheaumann Laser, Inc.  
45 Bartlett Street  
Marlborough, MA 01752  
Phone: 508-970-0600  
Fax: 508-481-9261

### **Contact:**

Katina Sousa  
Quality Systems Administrator  
Sheaumann Laser, Inc.  
45 Bartlett Street  
Marlborough, MA 01752  
Phone: 508-970-0600  
Fax: 508-491-9261  
Email: ksousa@sheaumann.com

### **Manufacturer:**

Sheaumann Laser, Inc.

### **Date Prepared:**

**March 12, 2015**

### **Trade Name:**

NeoLas

### **Common Name:**

ER-1

### **Product Code(s):**

GEX

### **Classification:**

Class II

### **Review Panel:**

**Predicate Devices (Claiming Substantial Equivalence):**

MEY-1-A

K120377

Picasso Lite

K102359

**Summary Description of Device:**

NeoLas is a portable, microprocessor controlled dual laser system with both ER:YAG and Soft Tissue capabilities. The NeoLas provides treatment capabilities via two separate fiber jumper and handpiece assemblies; NeoLas1 (ER:YAG) and NeoLas2 (Soft Tissue). The NeoLas1 treatment delivery system emits a 2.94um infrared photon pulses that used in the treatment of various endodontic and soft tissue indications. The NeoLas2 treatment delivery system utilizes solid-state diode laser (GaAlAs) technology to emit constant wavelength and pulsed energy of 808nm to perform soft tissue treatments.

**Intended Use/Indications for Use:**

The NeoLas ER:YAG laser and its accessories are intended for use in dentistry, dermatology and other surgical areas in the following procedures:

Endodontic Surgery (Root Amputation) Indications:

- Root end preparation for retrofill amalgam or composite
- Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex

**NOTE:** Any tissue growth (i.e. cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation

Laser Periodontal Procedures:

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage

- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Removal of granulation tissue from bony defects
- Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

The NeoLas 810nm Soft Tissue laser and its accessories are intended for use on adult and pediatric patients in dentistry, dermatology and other surgical areas in the following procedures:

Soft Tissue Indications including Pulpal Tissues\*

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Flap preparation—incision of soft tissue to prepare a flap and expose the bone.
- Flap preparation—incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
- Frenectomy and frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscesses
- Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery

- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulp extirpation
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex
- Root canal debridement and cleaning
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcer of the oral mucosa
- Vestibuloplasty

NOTE: Any tissue growth (i.e. cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation

**Performance Standards:**

This device is manufactured to comply with the performance standards promulgated by the FDA for products of this type and to the recognized consensus and safety standards listed below.

21 CFR 820; Quality Systems Regulations

21 CFR 1010.1-.5; Performance Standards for Electronic Products, General

21 CFR 1010.10; Performance Standards for Light-emitting Products, Laser Products

21 CFR 1040.11a; Performance Standards for Light-emitting Products, Medical Products

IEC 60601-1-2 Edition 3: 2007-03 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))

IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]. (Radiology)

## **Substantial Equivalence Summary:**

Few differences exist between the NeoLas and the predicate devices, AdvErL Evo Er:YAG Laser (MEY-1-A) (K120377) and Picasso Lite (K120359) as each of the NeoLas subsystems (NeoLas 1 and NeoLas 2) reflect similar specifications and treatment capabilities as their respective predicate comparisons. Additionally, the NeoLas and the predicate devices are GUI microprocessor controlled systems that deliver energy via reusable, flexible fiber-jumper assemblies and disposable tips.

The NeoLas1 ER:YAG laser subsystem and the AdvErL Evo Er:YAG Laser (MEY-1-A) are both ER:YAG 2.94um laser systems that reflect similar indications for use and specifications. Although there is a difference between the average output power of the AdvErL Evo Er:YAG Laser (MEY-1-A) and the NeoLas1 ER:YAG, Sheumann Laser, Inc. believes that this difference in performance does not raise any safety or efficacy concerns as the NeoLas has omitted the indications listed for the AdvErL Evo Er:YAG Laser (MEY-1-A) that require a higher output power from the statement of intended use. As the NeoLas1 ER:YAG subsystem reflects few differences in treatment capabilities, Sheumann Laser, Inc. believes there are no issues of safety or effectiveness that were not identified in the predicate device.

Furthermore, the NeoLas2 solid-state laser diode 810nm subsystem reflects no differences from the predicate device (Picasso Lite). As there are no differences between the two units in either the specifications or intended use, Sheumann Laser, Inc. believes there are no issues of safety or effectiveness that were not identified in the predicate device.

## **Nonclinical Tests:**

The disposable tips are provided sterile and have undergone testing for the Ethylene Oxide Sterilization chamber validation, process validation, verification of the effectiveness of biological indicators and revalidation testing to comply with sterilization requirements. Additionally, the disposable tips have been tested to validate the residual levels of EO and ECH in compliance with the recognized standards for the sterilization of healthcare products. The detachable fiber handpiece ends have been validated for sterilization by autoclaving consistent with the defined parameters in the FDA guidance document Reprocessing Medical Devices in Health Care Settings.