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

June 2, 2016

Precise Light Surgical
Mr. Ken Arnold
President And CEO
310 W. Hamilton Ave., Suite 210
Campbell, California 95008

Re: K160012
Trade/Device Name: O-pel Laser And Families Of Probe Delivery Devices
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: May 2, 2016
Received: May 4, 2016

Dear Mr. Arnold:

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,

Jennifer R. Stevenson -A

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

Indications for Use

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

510(k) Number *(if known)*
K160012

Device Name
O-pel Laser And Families Of Probe Delivery Devices

Indications for Use *(Describe)*
The O-pel laser and families of probe delivery devices are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including Arthroscopy, Urology, ENT, Dermatology, Plastic Surgery, General Surgery, Gastroenterology, Thoracic and Pulmonary and Gynecology.

ENT
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:
- Endonasal/sinus Surgery
- Partial Turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology and Plastic Surgery
Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:
- Basal cell carcinomas
- Lesions of skin and subcutaneous tissue
- Skin tags
- Plantar warts

General Surgery
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy

• Splenectomy
• Thyroidectomy
• Parathyroidectomy
• Herniorrhaphy
• Tonsillectomy
• Lymphadenectomy
• Partial Nephrectomy
• Pilonidal Cystectomy
• Resection of lipoma
• Debridement of Decubitus Ulcer
• Hemorrhoids
• Debridement of Statis Ulcer
• Biopsy

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue
• Laryngeallesions
• Airway obstructions including carcinoma
• Polyps and Granulomas
• Palliation of obstructing carcinomas of the tracheobronchial tree

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Urethral strictures
• Bladder neck incisions(BNI)
• Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors
• Ablation of Benign Prostatic Hypertrophy (BPH)
• Transurethral incision of the prostrate (TUIP)
• Laser resection of the prostate (HoLRP)
• Laser enucleation of the prostate (HoLEP)
• Laser ablation of the prostate (HoLAP)
• Condylomas
• Lesions of external genitalia

Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Appendectomy
• Polyps
• Biopsy
• Gall Bladder calculi
• Biliary/Bile duct calculi
• Ulcers
• Gastric ulcers
• Duodenal ulcers
• Non bleeding ulcers
• Pancreatitas
• Hemorrhoids
• Cholecystectomy
• Benign and Malignant Neoplasm
• Angiodysplasia
• Colorectal cancer
• Telangiectasias

• Telangiectasias of the Osler-Weber-Renu disease
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric erosions

Gynecology

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis)

• Intra-uterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation, and or vessel coagulation
• Soft tissue excision procedures such as excisional conization of the cervix

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

• Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including:
• Percutaneous Laser Disc Decompression/Discectomy
• Foraminoplasty
• Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery

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.

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510(k) Summary

Precise Light Surgical O-pel Laser and families of probe delivery devices

I SUBMITTER

Precise Light Surgical
310 W. Hamilton Ave Suite 210
Campbell, CA 95008
Phone: 844-669-1845
e-mail: karnold@preciselightsurgical.com

Contact person: Ken Arnold, President
Date prepared: December 30, 2015

Establishment Registration Number: TBD

II DEVICE

Name of Device: O-pel laser and families of Probe delivery devices

Common or Usual Name: 2 micron Laser System

Classification Name: Powered Laser Surgical Instrument and Accessories (21CFR 878.4810)

Regulatory Code: II

Product Code: GEX

III PREDICATE DEVICE(S)

K051167 Allmed RevoLix and RevoLix Jr
K011703 Modified Lumenis Versapulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers & Delivery Devices with Accessories

IV DEVICE DESCRIPTION

The O-pel laser is an infrared laser system with an output wavelength of approximately 2μm. The O-pel laser and families of probe delivery devices (O-pel laser system) have an Intended Use of cutting and coagulating tissue, specifically incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue. The O-pel laser system is comprised of the following components:

-a laser console
-control and display panel;
-a fiber port for delivery systems;

-a footswitch;
-a variety of fiber optic (probe) delivery devices

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- Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery

VI RATIONAL FOR SUBSTANTIAL EQUIVALENCE

The O-pel laser system with fiber optic delivery devices share the same intended use, indications for use, similar design features and functional features and therefore are substantially equivalent to the Allmed Revolix and the Lumenis VersaPulse systems.

VII PERFORMANCE DATA

Electromagnetic Compatibility. The laser console was tested to IEC 60601-1-2: 2007 by a third party and was found to comply.

Electrical Safety: The laser console was tested to IEC 60601-1: 2007 by a third party and was found to comply.

Laser Safety: The laser console was tested to IEC 60601-2-22 and IEC 60825-1: by a third party and was found to comply.

Coexistence: The laser console was tested to the FDA Guidance, "Radio Frequency Wireless Technology in Medical Devices" issued August 14, 2013 and was found to comply.

Biocompatibility. The biocompatibility evaluation of the Probe delivery device was conducted per FDA draft guidance document, "Use of International Standard ISO 10993, "Biological Evaluation of medical devices Part 1: Evaluation and Testing "" dated April 23, 2013. The following tests were performed:

ISO 10993-5: Biological Evaluation of medical devices Part 5- Tests for in vitro cytotoxicity
ANSI /AAMI/ISO 10993-7:2008 (R) 2012 Biological evaluation of medical device – Part 7 Ethylene Oxide sterilization residues.

VIII CONCLUSIONS

The O-pel laser and families of Probe delivery devices share the same indications for use, similar design features, and functional features and therefore are substantially equivalent to the predicate devices. Any differences in technological characteristics do not raise any new issues of safety or efficacy. Substantial equivalence was not based upon clinical performance.