June 28, 2018

OmniGuide, Inc
Sam Wade
Vice President, Regulatory Affairs and Quality Assurance
4 Maguire Road
Lexington, Massachusetts 02421

Re: K180993
Trade/Device Name: Beacon Advanced CO2 Laser System
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: April 13, 2018
Received: April 16, 2018

Dear Sam Wade:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180993

Device Name
Beacon CO2 Advanced Energy Laser System

Indications for Use *(Describe)*
The Beacon Advanced Energy CO2 Laser System Laser System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues in the following specialties: Dermatology, General Surgery, Gynecology, Head & Neck Surgery, Neurosurgery, Oral Surgery, Orthopedic Surgery in soft tissue, Otolaryngology, Plastic & Reconstructive Surgery, Podiatry, Urology.

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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Section 7: 510(k) Summary

General Provisions

510(k) Owner's Name:	OmniGuide, Inc.
Registration Number:	3005350457
Address:	4 Maguire Road
	Lexington, MA 02421
Contact Person:	Samuel D. Wade
	Vice President, Quality Assurance and Regulatory Affairs
Phone Number:	(617) 551 4810, Cell: (978) 844-7515
Fax Number:	(617) 551-8445
Classification Name:	Powered Laser Surgical Instrument
Regulation:	21 CFR §878.4810
Regulatory Class:	II
Product Code:	GEX
Proprietary Name:	Beacon Advanced Energy Laser System
Common Name:	Powered Laser Surgical Instrument

Name of Predicate Device(s)

- K151331 The UltraPulse system (UltraPulse and UltraPulse Duo models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO_2 Surgical Lasers)

Name of Reference Device(s)

- K093251 OmniGuide BeamPath®FELS 25A, CO_2 Laser System
- K100384 Lumenis FiberLase CO_2 Laser WaveGuide
- K945648 TTI Medical AccuBeam CO_s Laser Handpiece
- K864378 TTI CO_2 Laser Micromanipulator

Indications for Use

The Beacon Advanced Energy CO_2 Laser System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues in the following specialties: Dermatology, General Surgery, Gynecology, Head & Neck Surgery, Neurosurgery, Oral Surgery, Orthopedic Surgery in soft tissue, Otolaryngology (ENT), Plastic & Reconstructive Surgery, Podiatry, Urology

Intended Use

The Beacon Advanced CO_2 Advanced Energy Laser System is intended to be used in conjunction with the OmniGuide WaveGuide Fibers or the Articulated Arm to be used for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral soft tissues.

Device Description

The Beacon Advanced Energy Laser System is a carbon dioxide laser system utilizing RF excited CO_2 laser tube. The device is comprised of a system console, with or without an articulated arm terminated with a handpiece or a micromanipulator, a fiber adapter, system control electronics, a touch screen providing a graphical user interface, a covered footswitch, helium gas management system (for using the OmniGuide Waveguide fibers with the system (K140378, K093451, K093251 and K070157. Located in Appendix 6), and operating software.

The laser system delivers laser energy at 10,600 nm in three different output modes: continuous, single pulse and repeat pulse and two waveforms: Continuous Wave (CW) or Super Pulse (SP). The laser energy produced by the laser tube within the laser console is delivered through an articulated arm system terminating in a handpiece or multiple-use attachments or through a fiber adaptor coupling the laser energy into a OmniGuide waveguide. The articulating arm allows the laser energy to be delivered through a focusing handpiece or a micromanipulator achieving laser beam spot sizes in the range of 0.2-0.6 mm in the operating field. The Waveguide fibers have been cleared through K140378, K093451, K093251 and K070157.

The Beacon is operated and controlled via Graphical User Interface implemented by proprietary operating software running on single board computer in the laser console.

The operator can control various aspects of the Beacon operation through the Graphical User Interface on the touch screen. The access to the Graphical User Interface and laser operation is password protected to control access. The operator can adjust the lasing modes, pulse rate and duration in case of pulsed modes, set the waveform (CW or SP) and output power. They can also select whether to use fiber or the articulating arm with the micromanipulator or handpieces or other accessories.

Material used are mainly machined or cast aluminum, stainless steel, standard optics for the transmission or the reflection of the CO_2 laser wave energy. It is worth noting that all components (mirrors, lenses, fiber and articulating arm) that the CO_s light travels through are passive and do not alter the wavelength or any other of the fundamental properties of the CO_2 Laser.

Technological Characteristics

The Beacon has the same intended use and similar indications for use, technological characteristics and operating principles as K151331 The UltraPulse system (UltraPulse and UltraPulse Duo models, members of the modified Lumenis Family of UltraPulse SurgiTouch CO_2 Surgical Lasers). The design and components are very similar to the predicate device. Both devices have the Graphical User Interface on a touch screen in the front of the device. Each device has an articulating arm and an adapter port for the attachment of fibers. Both devices have the laser energy generated within the laser console and delivered to either the articulated arm or the fiber adapter. Each device has an aiming beam to assist in the proper delivery of the treatment beams but aiming beam does not deliver any therapeutic energy. Both devices have similar key design aspects including spot sizes, laser wavelength, ranges of laser operating parameters such as pulse widths and output power. The differences are minor and do not raise any new issues of safety or efficacy of the Beacon device as shown in the performance testing results.

Performance Data

Risk Analysis

Risk analysis was performed according to IEC 14971 and the FDA Guidance Document: Application of **risk management** to medical **devices** and reviewed by an independent third party (Intertek) and found to be in compliance.

Electrical Safety and Electromagnetic Compatibility and other standard testing

Evaluation of the device was conducted by an independent testing laboratory (Intertek) and was found in compliance:

- IEC 60601-1, Medical electrical equipment, Part 1 General requirements for basic safety and essential performance.
- IEC 62366 Medical devices- Application of usability engineering to medical devices
- IEC 60601-2-22 Third Edition 2007-05, Medical electrical equipment-Part2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1 Ed. 2.0 (2007), Safety of Laser Products- Part 1: Equipment classification and requirements
- IEC 62304:2006 Medical Device software- Software life cycle processes
- IEC 14971:2007/(R) 2010 Medical Devices- Application of Risk Management to Medical Devices
- IEC 60601-1 Medical Electrical Equipment, Part 1-6 General requirement for Safety: Collateral Standard Usability
- IEC 60601-1-2 ed 4. EMC

Non-Clinical Performance Data

The Beacon Advanced Energy CO_2 Laser System performance characteristics have been evaluated through testing and analysis of laser power output and beam quality. The ability of new device to withstand variant operation, storage and transportation conditions was tested. The system testing (energy measurements, safety controls, emission indicator, switching mechanism, fiber and articulating arm and aiming beam was also completed. This type of testing complies with the respective section of the FDA Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995) and is similar to the predicate device tests. The performance of the Beacon Advanced Energy CO_2 Laser System and related parameters of the predicate device are substantially equivalent.

Software verification and validation testing was conducted, and documentation provided as recommended by FDA's "Guidance for the Content of Premarket Submissions Contained in Medical Devices" and IEC 62304:2006 Medical Device Software. Device software verification and validation results were found acceptable for software release

Clinical Performance Data

Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as the predicate device

Biocompatibility

No part of the laser contacts the patient therefor no biocompatibility testing was necessary

Summary of Substantial Equivalence

The Beacon Advanced Energy CO_2 Laser System and the predicate device have the same intended use as surgical lasers with similar indications for use. The Beacon Advanced Energy CO_2 Laser System presents similar technological characteristics as its predicate device, including the laser type, wavelength, device design, waveforms and pulsed mode characteristics, laser beam spot sizes. Although there might be minor differences in the details of the device design, they are not sufficient to raise new questions of safety or efficacy.

Conclusion

The Beacon Advanced Energy CO_2 Laser System is as safe and effective as the Lumenis UltraPulse and UltraPulse Duo Laser Family (K151331). The new device has similar intended use and indications for use, technological characteristics and the same principle of operation as the predicate device. The minor differences in the indications for use do not alter the intended surgical use of the device and do not affect the safety or efficacy when used as labeled. The minor design differences raise no new issues of safety or efficacy. Thus, the Beacon Advanced Energy CO_2 Laser and the Lumenis UltraPulse and UltraPulse Duo are substantially equivalent.