DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 25, 2014

OmniGuide Incorporated
Ms. Nicole Rasmussen
Senior Regulatory Specialist
One Kendall Square, Suite B1301
Cambridge, Massachusetts 02139

Re: K140378
Trade Name: OmniGuide Laser System with FlexGuide™ Ultra
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: August 29, 2014
Received: September 2, 2014

Dear Mr. Rasmussen:

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 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.

Sincerely yours,

David Krause -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)*
K140378

Device Name
OmniGuide Laser System with FlexGuide™ Ultra

Indications for Use *(Describe)*
The OmniGuide Laser System with FlexGuide™ Ultra, which includes the FELS 25A Laser, BeamPath Fibers and the FlexGuide™ Ultra handpiece, is indicated for use to enable the surgeon to perform incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. This system is intended for use with a grasper in the following medical specialties: general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, urologic surgical procedures, otorhinolaryngology surgical 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)*

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

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"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."

510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. Submitter's Information

Name: OmniGuide, Inc.

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Suite B1301
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Fax: (617) 551-8445

Contact: Nicole Rasmussen
Sr. Regulatory Affairs Specialist

Date Prepared: September 24, 2014

2. Device Information

Trade/Proprietary Name: OmniGuide Laser System with FlexGuide™ Ultra

Common/Usual Name: Fiber Optic Handpiece
CO2 Laser Powered Surgical Instrument

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR § 878.4810)

Product Code: GEX

3. Predicate Devices

Handpiece: ***See Tables 1 & 2***
OmniGuide, Inc.
OmniGuide BeamPath Fiber Optic Handpiece System & Sterilization Tray
K081939

Laser: ***No Changes***
OmniGuide, Inc.
OmniGuide BeamPath FELS 25A CO2 Laser System
K093251

Fibers: ***No Changes, see Table 1.***
OmniGuide, Inc.
OmniGuide BeamPath CO2 Mark III WaveGuide Fiber
K070157

OmniGuide, Inc.
OmniGuide BeamPath CO2 Mark III WaveGuide Fiber w/Low Loss Tip
K093451

4. Intended Use

The OmniGuide Laser System with FlexGuide™ Ultra, which includes the FELS 25A Laser, BeamPath Fibers and the FlexGuide™ Ultra handpiece, is indicated for use to enable the surgeon to perform incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. This system is intended for use with a grasper in the following medical specialties: general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, urologic surgical procedures, otorhinolaryngology surgical procedures.

5. Device Description

The OmniGuide Laser System with FlexGuide™ Ultra, which includes the FELS 25A Laser, BeamPath Fibers and the FlexGuide™ Ultra handpiece are used together to perform the intended use above. The FELS 25A Laser and BeamPath Fibers remain unchanged. Additionally, the BeamPath fibers that deliver the laser energy, are cleared for laparoscopic use. The BeamPath Fiber Optic Handpiece (K081939) has been modified to the FlexGuide^{TM} Ultra handpiece, which includes a sterilization tray and are sold as non-sterile reusable devices. The FlexGuide Ultra is a flexible handpiece that consists of three main sections: the proximal rear sealing cap, handpiece body/cannula and distal tip. The material of the FlexGuide Ultra handpiece is stainless steel. The OmniGuide BeamPath fiber (K070157, K093451) is inserted through the flexible handpiece proximal rear sealing cap and is fixated so that it is visualized through two site holes at the handpiece distal tip. The OmniGuide FELS 25A Laser System (K093251) still generates the CO2 laser energy, which is transmitted through the fiber. During the procedure the surgeon grasps and holds the distal tip of the FlexGuide Ultra with a grasper. The FlexGuide Ultra distal tip may be used in either non-contact mode or contact mode. The surgeon may also use the distal tip to enable tissue manipulation.

6. Performance Testing

Performance testing has validated the FlexGuide Ultra handpiece. Engineering analysis and bench testing concluded that the FlexGuide Ultra can be grasped, manipulated and confirmed the modified handpiece does not affect its purpose and performance when compared to the OmniGuide predicate handpiece. Additionally, the review of the technical characteristics, indications for use, risk analysis,

verification and validation information provided in this 510(k) Premarket Notification demonstrates the OmniGuide FlexGuide Ultra handpiece, when used in conjunction with OmniGuide BeamPath fibers, are as safe and effective as its predicate device.

7. Substantial Equivalence

The FlexGuide Ultra Handpiece is substantially equivalent to its predicate device when used according to its intended use. This statement is based on the information provided in this 510(k) Premarket Notification which demonstrates the FlexGuide Ultra handpiece shares the similar intended uses, operating principles, similar technical characteristics and incorporates the same basic handpiece design when compared to the original cleared handpiece. The handpiece also shares a similar intended use as the predicate fibers, which are used in conjunction with the FlexGuide Ultra to transmit CO2 laser energy to the treatment site.

Table 1. Predicate Device Indications for Use Comparison

	OmniGuide Laser System with FlexGuide™ Ultra (K140378 *pending*)	**OmniGuide BeamPath Fiber Optic Handpiece System (K081939)**	**OmniGuide Beam Path CO 2 Mark III WaveGuide Fiber (K070157)**	**OmniGuide BeamPath CO2 Mark III WaveGuide Fiber w/Low Loss Tip (K093451)**
Indications for Use	The OmniGuide Laser System with FlexGuide™ Ultra, which includes the FELS 25A Laser, BeamPath Fibers and the FlexGuide™ Ultra handpiece, is indicated for use to enable the surgeon to perform incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. This system is intended for use with a grasper in the following medical specialties: general laparoscopic	The OmniGuide BeamPath® Fiber Optic Handpiece System and Sterilization Tray is indicated for use in conjunction with OmniGuide's waveguide fibers to enable the surgeon to perform incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry,	The OmniGuide Mark Ill WaveGuide Fiber is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology, and	The OmniGuide Beam Path CO 2 Mark II WaveGuide Fiber with Low Profile/Low Loss Tip is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indidated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology,

	surgical procedures, gynecologic laparoscopic surgical procedures, urologic surgical procedures, otorhinolaryngology surgical procedures.	dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology.	can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy. The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.	neurosurgery, urology, and pulmonology, and can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy. The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.

Table 2. Predicate Handpiece Specification Comparison

	OmniGuide Laser System with FlexGuide™ Ultra (K140378 *pending*)	**OmniGuide BeamPath Fiber Optic Handpiece System (K081939)**
Handpiece Lumen Material	304 Stainless Steel	304 Stainless Steel Hypodermic Tubing
Lumen Length	50cm	Up to 60cm
Handpiece Design	Distal tip, handpiece body/cannula, rear sealing cap	Distal tip, handpiece body/cannula, rear sealing cap

Distal Tip	Used in either non-contact mode or contact mode, and may be used to enable tissue manipulation.	Used in either non-contact mode or contact mode, and may be used to enable tissue manipulation.
Mechanism of Action	Handpiece is used to guide and protect BeamPath® fibers	Handpiece is used to guide and protect BeamPath® fibers
Operating Principle	To enable precision control and to stabilize surgeon hand motion	To enable precision control and to stabilize surgeon hand motion

8. Conclusions

OmniGuide conducted device performance non-clinical verification and validation testing. Results from the testing shows similar performance profiles when comparing the modified flexible handpiece to the original handpiece design. As confirmed in this 510(k) submission, testing was performed to confirm the modifications to the flexible handpiece when compared to its predicate device did not raise any new concerns of safety or effectiveness, alter the fundamental scientific technology of the device, nor affect its mode of use. OmniGuide believes the modified handpiece is substantially equivalent to its predicate handpiece based on similar specifications, performance data, intended use, and the handpiece mechanism of action. Thus, the FlexGuide Ultra handpiece is as safe, as effective and performs similar to the predicate handpiece.