January 14, 2021

OmniGuide, Inc.
David Johnson
Director, QA/RA
4 Maguire Road
Lexington, Massachusetts 02421

Re: K203241
Trade/Device Name: OmniGuide BeamPath OTO-U Fiber
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: December 15, 2020
Received: December 16, 2020

Dear David Johnson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva U. Pandya -S

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K203241

Device Name
OmniGuide Beam Path OTO-U Fiber for CO2 Laser Systems

Indications for Use *(Describe)*
The OmniGuide Beam Path OTO-U Fiber for CO2 Laser Systems is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissue. 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 can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngology, gastroscopy, colonoscopy, laproscopy, 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.

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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K203241

510(k) Summary

Submitter Information

Submitter Name:	OmniGuide, Inc.
Address:	4 Maguire Road Lexington, MA 02421 Telephone 617 551 8410
Registration Number:	3005350457
Date of Preparation:	11/01/2020

Subject Device

Trade Name:	OmniGuide® Beam Path OTO-U Fiber
Device:	CO_2 Laser Powered Surgical Instrument
Product Code:	GEX
Regulation Number:	21 CFR § 878.4810
Classification Name:	Laser Surgical Instrument for use in general and plastic surgery and in dermatology
Regulatory Class:	II

Predicate Device

Trade Name:	OmniGuide Beam Path OTO-M, OTO-S
Classification Name:	Laser Surgical Instrument for use in general and plastic surgery and in dermatology.
Predicate Premarket Notification:	K093451, K073313
Manufacturer:	OmniGuide, Inc.
	These two devices have not been subject to a design related recall.
Reference Device:	No reference devices were used in this submission
Purpose of Submission:	The purpose of the submission is to expand the product offering of the OTO product line to include a more flexible modified fiber body, a silver optical reflective coating the internal dimension of the fused silica, and modify the glass configuration of the existing cleared and marketed OTO product offering.

Device Description:

The OmniGuide Beam Path OTO-U Fiber is a single use laser surgical instrument provided sterile for use in transmitting laser energy at 10.6 µm from a CO_2 Laser System to a surgical site through an endoscope, flexible or rigid or using an accessory handpiece. It is connected to the laser system utilizing a standard ST II stainless steel fitting which is used by many laser manufacturers. The fiber has the following dimensions and composition:

Table 1. List of Fiber Components, Dimensions and Materials

Component	Dimensions	Material	Body Contact
ST II Laser Connector	17 mm L	Stainless Steel	No
Connector Insert (Ferrule)	128µm	Die Cast Stainless Steel	No
RFID Wing	1.18" W x 0.510"H x 0.512"D	Hytrel 6356	No
SMA Medical Boot	3.0 mm OD	USP Class IV Plastic	No
Fused Silica Core	600 ± 15µm OD	Silica	Yes
Silver Coated Bore	315 ± 10µm ID	Silver	Yes
Hard Clad Buffer	630 ± 15µm OD	Fluorinated Acrylate	Yes
Tefzel Jacket	1350 ± 70µm OD	Tefzel	Yes

Indications for Use

The OmniGuide Beam Path OTO-U Fiber for CO2 Laser Systems is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissue. 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 can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngology, 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.

Summary of Technological Characteristics:

The device consists of an optical fiber assembly. The main functional characteristic is a Silver coating reflector that reflects and thereby contains and guides $C0_2$ laser energy within the fiber. . Silver coating is applied along the ID of the cladded fused silica core, allowing 10.6 µm laser energy to be guided along the fiber length and onto a surgical location. The fused silica core is cladded with a thin layer of Fluorinated Acrylate. The core is sheathed with a Tefzel polymer layer.

Helium gas is flowed in the core to provide cooling of the fiber as needed and to prevent contamination of the fiber core.

The fiber assembly is 1 to 2 meters long and transmits at the CO_2 laser emission of 10.6 µm. The fiber can be used in single pulse mode, repeat pulse mode and CW mode. Power output is limited to 10 Watts.

The recommended distance between fiber tip and tissue is 3 mm and the recommended gas flow is less than 1 liters per minute.

Clinical Performance Data:

Clinical trials were not deemed necessary as the OTO-U is using similar technology, has the same indications for use and has the same intended use.

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Non-Clinical Bench Testing:

Biocompatibility:

Biocompatibility was performed on the OmniGuide Beam Path OTO-U Fiber per ISO 10993-1 and the FDA Guidance Document *Use of the International Standard ISO 10993-1, "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process, 2020* for a External communicating device contacting tissue/bone for a limited time of less than 24 hours. All the components are included in the legally marketed predicate or commonly used in 510(k) cleared marketed devices. Accordingly, biological testing included, and all testing met the requirements of the standards, USP requirements and FDA Guidance: Biocompatibility Data is in VOL_020

- Hemocompatibility:
    - ISO 10993-4 Biological Evaluation of Medical Device-Part 4 Selection of Tests for Interaction with Blood
    - ASTM F756-08, Standard Practice for the Assessment of Hemolytic Properties of Materials, 2008
- Cytotoxicity:
    - AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices-Part 5 Tests for invitro cytotoxicity
- Irritation/Intracutaneous:
    - ISO 10993-10 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization
- Acute Systemic Toxicity:
    - ISO 10993-11 Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity
- Pyrogen Test
    - USP Rabbit Pyrogen Study, Material Mediated

Sterilization Validation:

- Sterilization Validation
    - ISO 11135:2014 Amd:2018 Sterilization of Health Care Products
    - Testing met the requirements of the protocol and are available for review by FDA.

Cyber Security and Wireless Information:

- The OmniGuide Beam Path OTO-U Hollow Laser Fiber is not an electrical device and contains no computer. It contains passive RFID for product identification and authentication. There is no cybersecurity and wireless concerns because RFID is passive very short range (10mm RFID range) device and is recognizable by OmniGuide laser systems when plugged into the laser systems.

Software:

- There is no software associated or contained in the predicate or revised product**.** Therefore, there is no software documentation contained herein.

Functional Testing:

Functional Testing was performed to ensure the device was equivalent to the predicate devices and that the modified device met the requirements of the design Control Policy. All testing met the predetermined specifications. The requirements are documented below. Protocols and results are available for FDA inspection and review.

Summary of Substantial Equivalence:

The modified device, OmniGuide Beam Path OTO-U Fiber is substantially equivalent to the predicate marketed devices K093451 OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low profile/Low Loss Tip and K073313 OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile Tip in that it has the same indications for use, the same hollow internal lumen to propagate CO_2 laser energy and allow flow of helium gas. The OTO-U fiber has a silver coated internal lumen while the K093451 OmniGuide Beam Path Mark III Waveguide utilizes a glass photonic bandgap reflective lining. Both reflective linings serve the same purpose to allow propagation of laser energy at 10.6µm wavelength from a CO_2 Laser System with comparable transmission characteristics and providing similar laser power and laser spot size to surgical location. The OTO-U has an outer jacket of Tefzel while the OmniGuide Beam Path Mark III has an outer jacket of polyamide, both fibers have the same outside and length dimensions. Both service the same patient population. Both fibers have the same RFID tag providing information regarding power settings and identification. Both fibers have the same fittings to allow connection to a cleared CO_2 laser system.

It has been shown in this 510(k) submission that the differences between the OmniGuide Beam Path OTO-U and the predicate devices do not raise any questions regarding its safety and effectiveness as demonstrated in the biocompatibility testing, functional testing and validation testing, OmniGuide Beam Path OTO-U as designed and manufactured, is determined to be substantially equivalent to the referenced predicate

Predicate OmniGuide K093451 and K073313 are attached in Appendix 1 of K203241 for reference.