OmniGuide, Inc.
Samuel Wade
VP, Quality Assurance/Regulatory Affairs
4 Maguire Road
Lexington, Massachusetts 02412

May 2, 2019

Re: K183199
Trade/Device Name: TRIO Handpiece
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, GEI
Dated: April 18, 2019
Received: April 19, 2019

Dear Samuel 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

For Jennifer Stevenson,
Acting 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)*

K183199

Device Name
TRIO™ handpiece

Indications for Use *(Describe)*

The OmniGuide® TRIO™ handpiece is indicated for the electrosurgical coagulation of soft body tissues and suction of fluids in general and ENT surgical procedures for the specialties of General Surgery, Head and Neck Surgery, Otolaryngology, and Oral surgery (including intra-oral tissues). When used with the OmniGuide® BeamPath® Laser waveguide, it is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues for the added specialties of Dermatology, Gynecology, Neurosurgery, Orthopedic Surgery, Plastic & Reconstructive Surgery, Podiatry and 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.

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."

SECTION 7: 510(K) SUMMARY

General Provisions:

510(k) Owner's Name:	OmniGuide®, Inc.
Address:	4 Maguire Road Lexington, MA 02421, USA
Contact Person	Samuel D Wade, Vice President of Quality Assurance and Regulatory Affairs
Phone Number:	(617) 551-8410 Cell: (978) 844-7515
Fax Number:	(617) 551-8445
Classification Name:	Powered Laser Surgical Instrument (21 CFR §878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology, Product Code GEX/ 21 CFR §878.4400 Electrosurgical cutting and coagulation device and accessories, Product code GEI)
Proprietary Name:	OmniGuide® TRIO™ handpiece (Proposed name)
Common Name:	Powered Laser Surgical Instrument

Name of Predicate Devices:

- OmniGuide® BeamPath® Fiber Optic handpiece (Product Code: GEX, 510(k) Number: K081939)
- Karl Storz Endoscopy – America, Inc., Briner Bipolar Coagulation Suction Cannula (Product code: EOB, 510(k) Number: K962396/K960009)[1]
- Kirwan Surgical Products, Inc., Kirwan Bipolar Coagulation Forceps (Product code: GEI, 510(k) Number: K965241/K900533)[2]

Indications for Use:

The OmniGuide® TRIO™ handpiece is indicated for the electrosurgical coagulation of soft body tissues and suction of fluids in general and ENT surgical procedures for the specialties of General Surgery, Head and Neck Surgery, Otolaryngology, and Oral surgery (including intra-oral tissues). When used with the OmniGuide® BeamPath® Laser waveguide, it is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues for the added specialties of Dermatology, Gynecology, Neurosurgery, Orthopedic Surgery, Plastic & Reconstructive Surgery, Podiatry and Urology.

[1] Both 510(k) Numbers are included as we could not find the complete Summaries on the FDA releasable 510(k) database or FOI records
[2] Both 510(k) Numbers are included as we could not find the 510(k) Summary for K900533 on the FDA releasable 510(k) database or FOI records

Device Description:

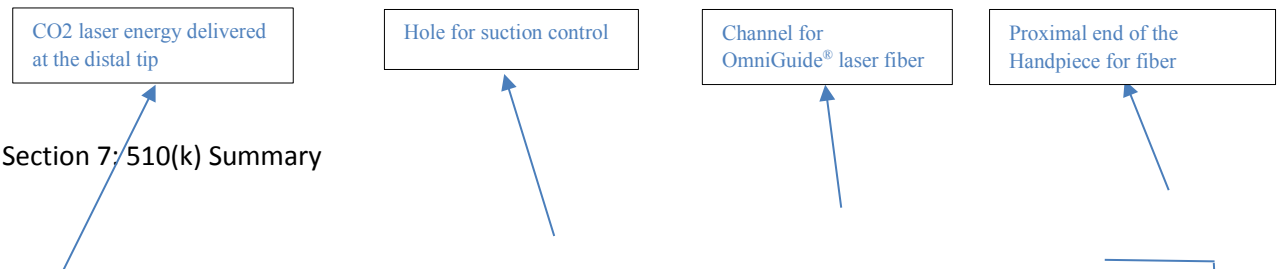
The TRIO™ handpiece is a handheld single use device designed to act as a laser waveguide guide/holder for previously cleared waveguides. The TRIO™ handpiece combines three fundamental surgical instrument functions into one lightweight and compact handheld disposable surgical instrument. It enables a surgeon to provide fluid suction, bipolar cautery, and CO_2 laser energy without the necessity of changing instruments, saving surgical time for both physician and patient and a corresponding reduction in cost. Laser energy is delivered via a flexible OmniGuide® fiber for minimally invasive surgery.

The instrument is provided sterile and is intended for single use only. The package has an accelerated shelf life of two years.

The sterile package includes a cable to connect the handpiece to an electrosurgical generator. The cables are generic in nature and several varieties available at a hospital/ office will function. The package also includes a small brush for cleaning coagulation tips with adhered material. The TRIO™ handpiece is intended to be used only with the family of OmniGuide® CO_2 Laser fibers including Velocity™, Elite™, and Select™ fibers previously cleared in 510(k) K070157.

The OmniGuide® handpiece is intended for use by licensed surgeons only for open surgical procedures listed in the indications for use. The objective of the handpiece is to enable precision control and to stabilize surgeon hand motion. The waveguide fiber is inserted through the proximal end of the handpiece and fixated so that it is observed at the handpiece's distal tip. The surgeon wields the handpiece as a pencil and advances the handpiece so that its distal tip is near the target tissue to exert the desired effect of the waveguide fiber: suction and coagulation. The surgeon may use the handpiece distal tip in either non-contact mode or contact mode and may use the distal tip to enable tissue manipulation, electrosurgical portion is used for coagulation due to bleeding during laser surgery or tissue manipulation.

The TRIO™ handpiece can be used with any Electro-Surgical Unit (ESU) with output power of up to 750 peak to peak voltage (Vp-p) and footswitch actuation. The instrument is provided with a 12-foot bipolar cable with fixed leads. The TRIO™ handpiece instrument can be used with any hospital or office suction apparatus. Fluid aspiration is controlled via a suction control port on the handle of the instrument.



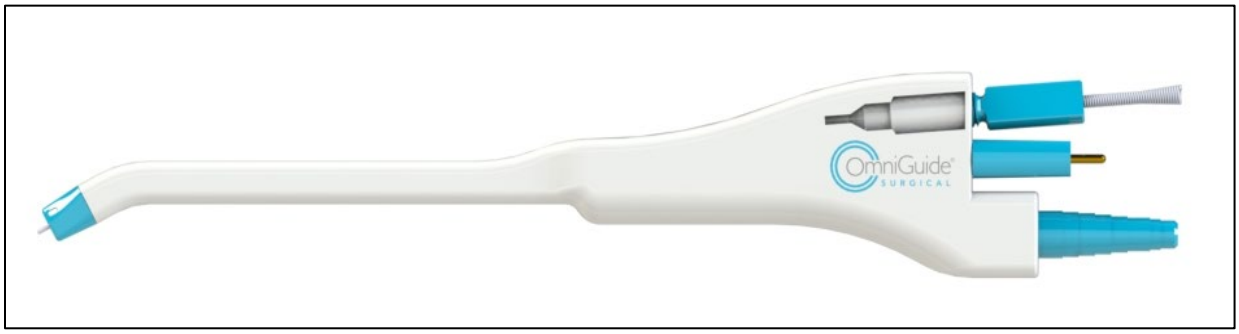


Figure 1: OmniGuide® TRIO™ Handpiece

Technological Characteristics:

The OmniGuide® TRIO™ handpiece has similar technological characteristics of the Briner Bipolar Coagulation Suction Cannula (K962396/K960009) and the Kirwan Bipolar Coagulation Forceps (K965241/K900533).

All use an electrosurgical generator to supply RF to the electrodes. The electrodes are similar in terms of dimensions and location at the distal end of the device. All three devices are designed to be handheld and use the same operating principles for electrocautery by bringing the electrodes into contact with the tissue.

BRINER and TRIO™ devices use wall suction through a 3/8" tube attached to the unit. Suction is performed by bringing the tip into contact with the fluid in the surgical field. Suction is controlled by closing or opening an aperture in the handle.

The TRIO™ is similar in function to the OmniGuide® BeamPath® fiber optic handpiece (K081939) in that both are used to facilitate delivery of laser energy through a previously cleared fiber optic waveguide (K140378 OmniGuide® Laser System with FlexGuide Ultra) allowing the surgeon to hold the waveguide and direct laser energy from the tip of the waveguide to the tissue. Both handpieces do not generate laser energy, they merely act as a support and guide the laser fiber to the surgical field.

The OmniGuide® TRIO™ handpiece system differs from the OmniGuide® BeamPath® fiber optic handpiece (K081939) in the use of construction materials. The TRIO™ is manufactured with materials suitable for disposable devices while the OmniGuide® BeamPath® fiber optic handpiece is constructed of stainless steel to allow for resterilization and multiple uses.

The TRIO™ handpiece differs from the Karl Storz Briner device and the Kirwan Bipolar Coagulation Forceps in the use of different construction materials and slightly different design characteristics, such as length, outer diameter of the cannula and geometry of the handle.

Electrical Safety and Electromagnetic Compatibility and other standard testing:

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

- IEC 60601-1, Medical electrical equipment, Part 1 General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- IEC 62366 Medical devices- Application of usability engineering to medical devices
- 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

Performance Testing Summary:

Safety and effectiveness of TRIO™ handpiece was established to be the same as the predicate devices and other similar devices on the market by performance testing. The ability of the handpiece was tested by performing user validation and bench-top testing such as beam clipping, suction, fiber retention, reliability, mechanical robustness and thermal profile.

Sterilization:

Sterilization Validation was performed which was successful and acceptable. It met the protocol and requirements specified in ISO 11135:2014.

Biocompatibility:

The following list of tests were performed to establish biocompatibility:

- Cytotoxicity: MEM Elution Test Serum MEM Extract in conformance with ISO 10993-5:2009 (Recognition Number 2-153), Biological evaluation of medical devices – Part 5: Tests for invitro cytotoxicity.
- ISO 10993-10:2010 Sensitization: Guinea Pig Maximization Test, Saline and Vegetable Oil Extracts

- ISO 10993-10:2002 (Recognition Number 2-87) Irritation: Intracutaneous Reactivity Test, Saline and Vegetable Oil Extracts
- ISO 10993-11:2006 (Recognition Number 2-118) Acute Systemic Toxicity: Systemic Injection Test, Saline and Vegetable Oil Extracts

The patient-contacting materials in the OmniGuide® TRIO™ handpiece passed these tests.

Packaging and Labeling:

The OmniGuide® TRIO™ handpiece is a sterile, single use only, prescription device, in a thermoformed tray along with a suitable cable to allow attachment to the handpiece and electrosurgical generator and the tray is heat sealed to a Tyvek lid. The tray with the Instructions for Use are inserted into a cardboard box imprinted with product information and labeling. The Package has a proposed shelf life of two years.

Conclusion:

The OmniGuide® TRIO™ Handpiece is as safe and effective as its predicates. The new device has similar intended use and indications for use, technological characteristics and principle of operation as the predicate devices. The 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 OmniGuide® TRIO™ Handpiece and its predicates are substantially equivalent.