December 23, 2019

Vortex Surgical Inc.
Gary Oliveros
Consultant
680 Crown Industrial Ct. Suite F
Chesterfield, MI 63005

Re: K191846
Trade/Device Name: MAXReach Laser Probe
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic photocoagulator
Regulatory Class: Class II
Product Code: HQB
Dated: November 13, 2019
Received: November 14, 2019

Dear Gary Oliveros:

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 control's 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,

for Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K191846

Device Name
Vortex Surgical MAXReach Laser Probe

Indications for Use *(Describe)*
MAXReach Laser Probe is indicated for use in laser endophotocoagulation procedures in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. The MAXReach Laser Probe is compatible with the following lasers: Alcon Constellation/Pure Point Lasers, Iridex GL Laser and Ellex Solitaire Laser

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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K191846

510 (k) Summary
Vortex Surgical MaxReach Laser Probe
Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name:	Vortex Surgical
Address:	680 Crown Industrial Court Suite F Chesterfield, MO 63005
Contact Person:	Bob Neu Director, Product Development and QA/RA Telephone Number: 314-971-3812 Fax: 636-778-4352 Email: rneu@vortexsurgical.com
Regulatory Contact:	Gary Oliveros Regulatory Consultant Telephone Number – 636 219-5090 Email: goliveros1@att.net
510 (k) Number:	K191846
Date Prepared:	December 23, 2019
Device Trade Name:	Vortex Surgical MAXReach Laser Probe
Common Name:	Single Use Endo Ocular Laser Probe
Device Classification:	Class II
Regulation Number:	21 CFR 886.4690
Classification Name:	Photocoagulator and Accessories
Product Code:	HQB
FDA Panel:	Ophthalmic
Predicate Device:	Ophthalmed Directional Laser Probe, K142830

Device Description:

MAXReach Laser Probe is a sterile, single use medical device used for delivering laser endophotocoagulation into the posterior segment of the eye.

The laser probe is a cable made from one fiberoptic, one laser connector, one handle for surgeon manipulation, stainless steel tubing extending from the handle which penetrates the surgical site, and protective sheath over the fiber. On one side, the distal side, the fiberoptic is terminated by a connector that attaches to the laser console. On the other side, it is terminated by Nitinol tubing which penetrates the eye. It can be either 23ga or 25ga. The fiber for laser transmission is made from glass and is restricted for use with the wavelength of 500nm to 1100nm. The total length of the device is 101 inches. The total length of the fiber is 96 inches.

Indications for Use:

MAXReach Laser Probe is indicated for use in laser endophotocoagulation procedures in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. The MAXReach Laser Probe is compatible with the following lasers: Alcon Constellation/Pure Point Lasers, Iridex GL Laser and Ellex Solitaire Laser

Comparison of Technical Characteristics:

Technical Characteristics	Vortex Surgical MAXReach Laser Probe – K191846	Ophthalmed Directional Laser Probe - K142830
Indications for Use	MAXReach Laser Probe is intended to perform laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. The MAXReach Laser Probe is compatible with the following lasers: Alcon Constellation/Pure Point Lasers, Iridex GL Laser and Ellex Solitaire Laser.	Ophthalmed Bending Laser Probe is intended to perform laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm
Intended Use	The device is intended to perform laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery.	The device is intended to perform laser endophotocoagulation in the posterior segment of the eye during vitreoretinal surgery.
Wavelength	500 nm – 1100nm	500 nm – 1100nm
Optical Fiber	Glass Optical Fiber	Glass Optical Fiber
Distal End	304 Stainless Steel with Nitinol Tubing	304 Stainless with PEEK
Jacketing	PVC to protect the glass fiber	PVC to protect the glass fiber
Connector	905 SMA	905 SMA
Proximal End - Handle	Plastic Handle - Delrin	Plastic Handle
Overall Length	101 inches	101 inches
Cord Length	96 inches	96 inches
Biocompatibility	Cytotoxicity Sensitization Irritation Acute Systemic Toxicity	Cytotoxicity Sensitization Irritation

Technical Characteristics	Vortex Surgical MAXReach Laser Probe – K191846	Ophthalmed Directional Laser Probe - K142830
	Pyrogenicity	
Sterilization	Ethylene Oxide in accordance with ISO 11135	Ethylene Oxide in accordance with ISO 11135
Sterility Testing	Complies with FDA Guidance Document Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices	Not known
Shelf Life	3 years	3 years

Risk Management:

Risk Management has been implemented for the Vortex Surgical MaxReach Laser Probe and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices. The Vortex Surgical MAXReach Laser Probe is as safe and effective as the predicate device when used as intended.

Summary of Non-Clinical Bench Testing:

Non-Clinical bench testing was performed on both the Vortex Surgical MaxReach Laser Probe and the predicate device. The Non-Clinical Bench Testing included laser output, laser spot size, laser compatibility, ophthalmic cannula interface, and handle actuation testing. The results of the testing indicate the Vortex Surgical MaxReach Laser Probe operates in a similar fashion as the predicate and ensures the Vortex Surgical MaxReach Laser Probe is as safe and effective as the predicate device.

Conclusion:

The Non-Clinical bench testing indicates the device performance for the Vortex Surgical MaxReach Laser Probe is substantially equivalent to the predicate device. Vortex Surgical has demonstrated through, sterility testing, biocompatibility testing, shelf-life testing and non-clinical bench test results that the Vortex Surgical MaxReach Laser Probe is safe and effective as the predicate device and the slight differences between the two raise no new issue of safety or effectiveness.