November 3, 2022

Vortex Surgical Inc
Andrew Ritts
Director of Regulatory Affairs
680 Crown Industrial Ct Ste F
Chesterfield, MO 63005

Re: K220263
Trade/Device Name: Vortex Surgical Laser Probes, Vortex Surgical Illuminated Laser Probes, Vortex Surgical Endoilluminators, Vortex Surgical Chandeliers
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic Photocoagulator
Regulatory Class: Class II
Product Code: HQB, MPA
Dated: September 26, 2022
Received: September 26, 2022

Dear Andrew Ritts:

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,

Anjana Jain, PhD
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220263

Device Name
Laser Probe, Illuminated Laser Probe, Endoilluminator, and Chandelier

Indications for Use *(Describe)*
Vortex Surgical Laser Probes and Illuminated Laser Probes are indicated for use in laser endophotocoagulation procedures in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. Vortex Surgical Illuminated Laser Probes, Endoilluminator, and Chandelier are indicated for illumination during vitreoretinal surgery with visible light.

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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510(k) SUMMARY K220263

Submitted in accordance with the requirements of 21 CFR 807.92

Submitter name: Vortex Surgical Inc
Address: 680 Crown Industrial Court, Suite F
Chesterfield, MO 63005
Telephone number: 636-778-4350
Contact person: Andrew Ritts

Date: 1-20-2022
Name of device: Vortex Surgical Laser Probes, Vortex Surgical Illuminated Laser Probes, Vortex Surgical Endoilluminators, Vortex Surgical Chandeliers
Common name: Laser Probes, Illuminated Laser Probes, Endoilluminators, and Chandeliers
Classification name: Ophthalmic Photocoagulator
Regulatory class: II
Product Codes: HQB, MPA

The primary predicate device for the Vortex Surgical Laser Probe, Illuminated Laser Probe, Endoilluminator, and Chandelier is described below:

Predicate Device/Trade Name:	MAXReach Laser Probe
Common Name:	Ophthalmic Laser
Vortex Branded Name:	Direct Flex Laser Probe
510(k) Number:	K191846
Regulatory class:	II
Product Codes:	HQB
Regulation Number:	21 CFR 886.4690
Manufactured by:	Vortex Surgical

Device Description

Vortex Surgical Illuminated Laser Probe is a sterile, single use medical device used for delivering laser endophotocoagulation with illumination into the posterior segment of the eye.

Vortex Surgical Laser Probe is a sterile, single use medical device used for delivery 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, nitinol, PEEK, or stainless steel tubing extending from the handle which penetrates the surgical site, and protective sheath over the fiber. The MAXReach model device also contains a slide button allowing the surgeon to bend the nitinol, PEEK, or stainless steel tubing once inside the eye to direct output into the periphery of the eye. On the proximal end the fiberoptic is terminated by a connector that attaches to the laser console. On the distal side, the fiberoptic is terminated by nitinol, PEEK, or stainless steel tubing which penetrates the eye. The probe can be either 23ga, 25ga, or 27ga. The fiber for laser transmission is made from silica glass and is restricted for use with the wavelength of 500nm to 1100nm. In illuminated laser probes, the illumination fiber is made of PMMA. The total length of the device is 90 ± 6 inches.

Vortex Surgical Endoilluminator and Chandelier are sterile, single use medical devices used for delivering illumination into the posterior segment of the eye.

The endoilluminator is an illuminators made from one fiber optic cable, one handle for surgeon manipulation, stainless steel tubing extending from the handle which penetrates the surgical site, and the protective sheath over the fiber. On the proximal side the fiberoptic is terminated by a connector that attaches to the illumination console. The endoilluminator utilizes a needle. The illumination fiber is made of PMMA. The total length of the devices is 90 ± 6 inches.

The chandelier is an illuminator made from one fiber optic cable and the protective sheath over the fiber. The illumination fiber is made of PMMA. The total length of the devices is 90 ± 6 inches.

Intended Use

Vortex Surgical Laser Probes and Illuminated Laser Probes are indicated for use in laser endophotocoagulation procedures in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. Vortex Surgical Illuminated Laser Probes, Endoilluminator, and Chandelier are indicated for illumination during vitreoretinal surgery with visible light.

Compared to the predicate the indication for use does not have the compatible laser source systems. This information is provided in the instructions for use section in the step for connecting to the laser source. Changing the location of the compatible laser source systems is not critical to the intended surgical use of the device and do not affect the safety and effectiveness when used as labeled.

Substantial Equivalence

	Subject Device Vortex Surgical Laser Probe	Predicate Vortex MAXReach K191846
Laser Compatibility	Alcon Constellation/Pure Point Lasers, Iridex GL Laser, Ellex Solitaire Laser, and DORC EVA	Alcon Constellation/Pure Point Lasers, Iridex GL Laser, and Ellex Solitaire Laser
Illumination Compatibility	DORC EVA, B&L Stellaris, Alcon Constellation	None
Classification	II	II
Product Code	HQB	HQB
Regulation	886.4690	886.4690
Optical Fiber	Silica Glass optical fiber	Silica Glass optical fiber
Distal End	23ga, 25ga, or 27ga made from Nitinol, PEEK, or 304 Stainless Steel	23ga or 25ga made from Nitinol, PEEK, or 304 Stainless Steel
Jacketing	PVC	PVC
Connector	905 SMA	905 SMA
Main Components	Needle, Handle, Gauge Indicator, Fiber Cable 1[1], Connector 1[1], Snap Button[2], Front Needle[3], Fiber Cable 2[4], Connector 2[4]	Needle, Handle, Collar, Fiber Cable 1, Connector 1, Snap Button, Front Needle
Model Types	Straight, Curved, Flex-Tip, MAXReach	MAXReach only
Single Use	Yes	Yes
Target Population	Age 18-75	Age 18-75
Materials (Patient contacting)	Stainless Steel, Nitinol, PEEK, Silica Glass, Polyimide	Stainless Steel, Nitinol, Silica Glass, Polyimide
Anatomical Sites	Eye	Eye
Sterilization	Ethylene Oxide (ISO 11135)	Ethylene Oxide (ISO 11135)
Packaging	Tray, Tyvek Pouch	Tray, Tyvek Pouch

[1] Laser models only ; [2] Only on MAXReach Models ; [3] Only on Flex-Tip and MAXReach models ; [4] Illumination models only

Risk Management

Risk Management has been implemented for the Vortex Surgical Laser Probe Family and complies with ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices. The Vortex Surgical Laser Probe Family, including illumination devices are as safe and effective as the predicate devices they are compared with when used as intended.

Performance

The performance of the Vortex Surgical Laser Probes, Illuminated Laser Probes, Endoilluminators, and Chandeliers show that the instruments are substantially equivalent to their predicates. Vortex Surgical had

demonstrated through Ethylene Oxide (EO) sterilization validation, EU residual testing, endotoxin testing, biocompatibility testing, shelf-life testing, and nonclinical bench test results that the Vortex Surgical instruments are safe and effective as their predicate devices and any difference between the two raise no new issue of safety or effectiveness. The non-clinical bench testing for laser probes included, laser output (IEC 60601-2-22), laser spot size, laser compatibility, Ophthalmic cannula interface, and handle actuation testing (for MAXReach models). Non-clinical bench testing for illuminated instruments included measurement of time to exceed 10 J/cm^2 on illumination sources (ANSI Z80.36-2016) in comparison to their predicates. All products were accessed for biocompatibility utilizing ISO 10993-1.

Vortex Surgical Illuminated Laser Probe is an externally communicating device with limited (≤24 hrs.) tissue contact. The biocompatibility assessment was performed per 2020 FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' and included evaluation of cytotoxicity (elution method), sensitization (Guinea pig maximization testing), intracutaneous reactivity, acute systemic toxicity, and material mediated pyrogenicity.

Conclusions

The performance of the Vortex Surgical Laser Probes, Illuminated Laser Probes, Endoilluminators, and Chandeliers show that the instruments are substantially equivalent to its predicate. Vortex Surgical has demonstrated through Ethylene Oxide (EO) sterilization validation, EO residual testing, endotoxin testing, biocompatibility testing, shelf-life testing, and non-clinical bench test results that the Vortex Surgical instruments are safe and effective as their predicate devices and any differences between the two raise no new issue of safety or effectiveness.