April 3, 2025

Beaver-Visitec International, Inc.
Christopher Brady
Manager, Regulatory Affairs
500 Totten Pond Rd, 10 CityPoint
Waltham, Massachusetts 02451

Re: K240615
Trade/Device Name: Leos Laser and Endoscopy System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: February 28, 2024
Received: February 28, 2024

Dear Christopher Brady:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
Assistant Director
DHT1A: Division of Ophthalmic Devices
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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)*
K240615

Device Name
Leos Laser and Endoscopy System

Indications for Use *(Describe)*
The Leos system is indicated for intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do not allow a posterior view.

Glaucoma - This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures.

Vitreoretinal Surgery - The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation:
- During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites.
- To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies.
- To perform intraoperative retinal photocoagulation on a scleral buckle.
- To perform intraoperative photocoagulation around focal neovascularization.

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.

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I. Submitter Information

Date Prepared	April 2, 2025
Applicant	Beaver-Visitec International, Inc. 500 Totten Pond Rd - 10 CityPoint Waltham, MA 02451
Primary Correspondent	Christopher Brady Senior Manager, Regulatory Affairs cbrady@bvimedical.com 1-617-888-0007
Alternate Correspondent	Mattia Ronchetti Senior Director, Global Clinical and Regulatory Affairs mronchetti@bvimedical.com (+39) 3667597049

II. Subject Device

Device Common Name	Ophthalmic Laser and Endoscopy System
Trade/Proprietary Name	Leos Laser and Endoscopy System
Device Class	Class 2
Regulation Number	886.4390 – Ophthalmic Laser
Product Code	HQF – Laser, Ophthalmic

III. Predicate Devices

Primary Predicate	
Device Common Name	Ophthalmic Laser and Endoscopy System
Trade/Proprietary Name	Uram Ophthalmic Laser Endoscope
510(k) Number	K910532
Device Class	Class 2
Regulation Number	886.4390 – Ophthalmic laser
Product Code	HQF – Ophthalmic laser
Secondary Predicate	
Device Common Name	Ophthalmic Laser and Endoscopy System
Trade/Proprietary Name	E2 Microprobe Laser and Endoscopy System
510(k) Number	K042918
Device Class	Class 2
Regulation Number	878.4810 – Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code	GEX – Powered Laser Surgical Instrument

IV. Device Description Summary

The Leos Laser and Endoscopic System is a next generation ophthalmic laser and endoscopy system used for the treatment of glaucoma, vitreoretinal diseases, and intraocular visualization. The system contains an 810 nm powered diode laser delivered by the stainless-steel endoscopic laser probe (trade name: VueProbe), which is placed into eye tissue to illuminate and visualize the target tissue and deliver laser energy under direct visualization. The console is a fully integrated

portable device, containing a laser module assembly, viewing and control monitors, and a wireless footswitch for activating the laser. The larger passive monitor is for viewing the endoscopic video image and key treatment information, while the smaller touchscreen is used for parameters selection, rotation and viewing. The camera chip uses CMOS technology and is located at the tip of the probe. The LED light source is located within the plastic handpiece of the probe and illumination fibers carry the light to the tip. Additionally, the probe contains a laser fiber within its full length.

V. Indications for Use

The Leos system is indicated for intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do not allow a posterior view.

Glaucoma - This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures.

Vitreoretinal Surgery - The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation:

- During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites.
- To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies.
- To perform intraoperative retinal photocoagulation on a scleral buckle.
- To perform intraoperative photocoagulation around focal neovascularization

VI. Substantial Equivalence Comparison

The Leos System is designed to provide the same clinical therapy using the same treatment laser and aiming laser technologies and wavelengths as the predicate devices. The primary differences for the Leos System are updated endoscopy technology and new form factors for the console, footswitch and probe. A comparison table is provided below.

Characteristic	Uram Ophthalmic laser Endoscope and E2 Microprobe Laser and Endoscopy System (Predicate Devices) K910532, K042918	Leos Laser and Endoscopy System (Subject Device)	Same or Equivalent
Generic Device Description	810 nm Laser Endoscopy System	810 nm Laser Endoscopy System	Same
Indications	The ophthalmic laser endoscope is indicated for intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do allow a posterior view. **Glaucoma** - This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures. The endophotocoagulalion of ciliary processes under direct endoscopic view is highly controllable, i.e. titratable, and has been demonstrated to be effective in the treatment of glaucoma. **Vitreoretinal Surgery** - The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation:	The Leos System is indicated for intraoperative photocoagulation of the ciliary processes in the treatment of glaucoma, proliferative retinopathies, retinal detachment, and for evaluation of the internal ocular structures in patients with dense opacifications of the anterior segment which do not allow a posterior view. **Glaucoma** - This instrument is indicated for the treatment of glaucoma in patients who have failed with conventional topical and systemic medications, or previous laser photocoagulation, or trabeculectomy and other filtering procedures, or cyclocryotherapy or other cyclodestructive procedures. **Vitreoretinal Surgery** - The endoscopically controlled endophotocoagulation that is possible with the ophthalmic laser endoscope is also useful for endophotocoagulation: · During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites. · To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies.	Same, with minor changes (changes underlined) 1. Specify system 2. Correction at the end of first paragraph 3. Removal of third paragraph based on FDA feedback to remove performance claim

Characteristic	E2 System (Predicate Device) K042918, K910532	Leos System (Subject Device)	Same or Equivalent
	· During vitreous surgery to produce chorioretinal scar around retinal breaks or retinotomy sites. · To perform intraoperative panretinal photocoagulation (PRP) in proliferative retinopathies. · To perform intraoperative retinal photocoagulation on a scleral buckle. · To perform intraoperative photocoagulation around focal neovascularization	· To perform intraoperative retinal photocoagulation on a scleral buckle. · To perform intraoperative photocoagulation around focal neovascularization	
Camera Characteristics			
Visualization Delivery System	In probe - Fiberoptic Endoscope Video Camera Imaging	In probe - Direct Endoscope Video Camera Imaging	Same
Camera Location	Console	Endoscopic Probe	Equivalent Different location and camera signal
Camera Type	Analog, CCD	Digital, CMOS	Equivalent Different camera technologies

Characteristic	E2 System (Predicate Device) K042918, K910532	Leos System (Subject Device)	Same or Equivalent
Image Resolution	10,000 pixels (limited by fiber count)	40,000 pixels	Equivalent Leos System performance exceeds the E2 System
Laser Characteristics			
Treatment Laser Source and Type	Double hetero-structure, Gallium-Arsenide (GaAs), Semiconductor Diode (near-infrared spectra), Class IV	Double hetero-structure, Gallium-Arsenide (GaAs), Semiconductor Diode (near-infrared spectra), Class IV	Same
Treatment Laser Beam Nominal Wavelength (λ)	810 nm (subvisible)	810 nm (subvisible)	Same
Treatment Beam	Continuous Wave	Continuous Wave	Same
Treatment Modality	Continuous or Duration-Timed Modes	Continuous or Duration-Timed Modes	Same
Treatment Laser Power Range	0 – 1.2 Watts	0.05 – 1.2 Watts	Equivalent Removed lower setting of 0 Watts
Laser Power Settings	50 mW increments	50 mW increments	Same
Laser Power Accuracy	+/- 20%	+/- 20%	Same
Laser Duration Cycle Settings	Duration increments in seconds as follows: 0.05, 0.07, 0.10, 0.20, 0.30, 0.50, 1.0, 2.0, Continuous	Duration increments in seconds as follows: 0.05, 0.07, 0.10, 0.20, 0.30, 0.50, 1.0, 2.0, Continuous	Same

Characteristic	E2 System (Predicate Device) K042918, K910532	Leos System (Subject Device)	Same or Equivalent
Repetition Mode	No	No	Same
Adjustable Laser Spot Size	Not adjustable	Not adjustable	Same
Laser Footswitch Control	Wired control to activate laser and (optional) illumination intensity	Wireless control to activate laser and rotation	Equivalent The Leos footswitch does not include an option for illumination control and is wireless. Rotation control is an additional feature to be used based on user preference
Aiming Beam Laser Source and Type	Multi-quantum well structure, Aluminum Gallium Indium Phosphide (AlGaInP) Semiconductor Diode (visible spectra), Class III	Multi-quantum well structure, Aluminum Gallium Indium Phosphide (AlGaInP) Semiconductor Diode (visible spectra), Class III	Same
Aiming Beam Nominal Wavelength (λ)	640 nm (red/orange)	640 nm (red/orange)	Same
Aiming Beam Laser Power	up to 1500uW	up to 60 uW	Equivalent Less power required for equivalent aiming beam visibility due to new camera sensitivity, aperture and location.
Aiming Beam Laser Intensity Setting	10 – 250 in increments of 10	up to 100%, 11 settings between 5 and 100%	Equivalent

Characteristic	E2 System (Predicate Device) K042918, K910532	Leos System (Subject Device)	Same or Equivalent
			Settings changed to percentage scale and number of settings reduced
Illumination Characteristics			
Light Source	Xenon lamp [to probe from console]	LED illumination [in probe]	Equivalent New light source location and technology
Light Power	175 W	0.36 W LED driver	Equivalent Change due to difference in light source
Light Intensity	Mechanical shutter-wheel control knob (fully open to fully closed)	Touchscreen adjustable from 0 to 100% (manually or via an automatic adjustment algorithm)	Equivalent Change due to difference in light source and technology
Other Characteristics			
Interface	Table-top Console	Integrated standing control modules with console, touchscreen control screen, and passive view screen for surgeon	Equivalent Updated user interface
Communications – User Access	N/A	USB 2.0 Type A for video image recording and an HDMI port for a second passive viewing screen	Equivalent New features

Characteristic	E2 System (Predicate Device) K042918, K910532	Leos System (Subject Device)	Same or Equivalent
System Power	115 or 240 V AC, 60-50Hz	120 or 240 V AC, 60-50Hz	Same Both are standard US and worldwide power supply voltages
Probe Use Description	Reusable, non-sterile	Single use, sterile	Equivalent Probe will be provided sterile
Probe Options	20G, straight	19G, straight and curved	Equivalent Slight increase in size and curved option added based on user preference. No clinical/therapy difference

VII. Non-Clinical Tests Summary

Bench Testing

The following non-clinical testing was performed to support the substantial equivalence of the Leos System and VueProbe to the legally marketed predicate devices:

Electromagnetic Compatibility and Electrical Safety

- The Leos System was evaluated for EMC and electrical safety and found to be compliant with IEC 60601-1 for electrical safety and IEC 60601-1-2 for EMC.

Laser Safety and Optical Safety

- The Leos System was evaluated for laser and optical safety and found to be compliant with IEC 60825-1, IEC 60601-2-22, ANSI Z80.36.

Design Verification and Validation Testing

- Design verification testing confirms that the product meets its product requirements.

Software Verification and Validation

- The software level of concern is “Major”. Software verification and validation testing was completed successfully following FDA’s guidance “Guidance for the Content of premarket Submissions for Software Contained in Medical Devices” and IEC 62304.

Biocompatibility Testing

- Biocompatibility testing was performed per ISO 10993 and the sterile, single use probes were confirmed to be compliant to FDA recognized standards.

Sterilization and Shelf Life

- Sterilization, shelf life, and packaging/transport testing was performed to support the stated shelf life of the probes per FDA recognized standards ASTM D4169-22, ISO 11135, ISO 10993-7, AAMI TIR 28, and ISO 11607-1.

Animal Testing

Not applicable. Animal studies were not required to establish substantial equivalence.

Clinical Testing

Not applicable. Clinical studies were not required to establish substantial equivalence.

VIII. Conclusion

The Leos Laser and Endoscopy System is substantially equivalent to the predicate devices, Uram Ophthalmic Laser Endoscope (K910532) and E2 Microprobe Laser and Endoscopy System (K042918). The Leos system has identical indications for use as the predicate devices and is similar in technological characteristics, performance, and principles of operation. The differences between the subject device and the predicate devices do not raise any new safety or effectiveness concerns.