September 22, 2023

Carl Zeiss Meditec Inc
Tanesha Bland
Sr. Regulatory Affairs Specialist
5300 Central Parkway
Dublin, California 94568

Re: K230350
Trade/Device Name: VISULAS yag
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 16, 2023
Received: August 16, 2023

Dear Tanesha Bland:

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,

Bennett N. Walker -S

Digitally signed by Bennett N. Walker -S
Date: 2023.09.22 10:23:07 -04'00'

for Claudine Krawczyk
Acting 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)*
K230350

Device Name
VISULAS yag

Indications for Use *(Describe)*
VISULAS yag is intended for use in photodisrupting ocular tissue in the treatment of diseases of the eye, including Posterior capsulotomy, Iridotomy and Posterior Membranectomy.

This device is for Prescription Use (Rx) only.

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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In accordance with 21 CFR 807.92 the 510(k) Summary for the VISULAS yag is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec Inc 5300 Central Parkway Dublin, CA USA
Primary Correspondent	Tanesha Bland Sr. Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (925) 216-7963 Phone E-mail: tanesha.bland@zeiss.com (preferred)
Secondary Correspondent	Ling Ren Regulatory Affairs Manager Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena, Germany
Date Prepared:	September 22, 2023

2. SUBJECT DEVICE

Device Trade Name:	VISULAS yag
Classification:	21CFR886.4390 laser, Ophthalmic
Regulatory Class:	II
Product Code:	HQF

3. PREDICATE DEVICE

Predicate Device:	Ellex YAG Laser (Ultra Q, Ultra Q Reflex) (K212630)
Classification:	21CFR886.4390 Ophthalmic Laser
Regulatory Class:	II
Product Code:	HQF

4. DEVICE DESCRIPTION

VISULAS yag uses a Q-switched, flashlamp-pumped solid-state laser for photodisruption treatments of diseases of the eye, including posterior capsulotomy, iridotomy and membranectomy. Laser radiation is generated by means of a neodymium-doped yttrium aluminum garnet (Nd:YAG) gain medium inside the laser source. The emitted laser radiation with a near-infrared wavelength of $\lambda = 1064$ nm has a pulse duration of < 4 ns (full-width half-maximum; FWHM) and a focal diameter of 6.5 µm ± 20%. The maximum energy output per pulse is 9 to 13 mJ in single-burst mode.

5. INDICATIONS FOR USE

VISULAS yag is intended for use in photodisrupting ocular tissue in the treatment of diseases of the eye, including Posterior capsulotomy, Iridotomy and Posterior Membranectomy.

This device is for Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

Table 1. Subject to Predicate Device Comparison Table – Indications for Use

Device	Subject Device	Primary Predicate Device (K212630)	Equivalency Analysis
Indications for Use	VISULAS yag is intended for use in photodisrupting ocular tissues in the treatment of diseases of the eye, including: • Posterior capsulotomy • Iridotomy • Posterior Membranectomy	In the YAG mode (Ultra Q, Ultra Q Reflex): • Iridotomy and iridectomy • Posterior capsulotomy • Posterior membranectomy	The indication of VISULAS yag is equivalent to that of the reference device.

Table 2. Subject to Primary Reference Device Comparison Table – Indications for Use

Device	Subject Device	Primary Reference Device (K042139)	Equivalency Analysis
Indications for Use	VISULAS yag is intended for use in photodisrupting ocular tissues in the treatment of diseases of the eye, including: • Posterior capsulotomy • Iridotomy • Posterior Membranectomy	This device will be used in ophthalmic applications, including posterior capsulotomy and peripheral iridotomy. This device is intended for use primarily by physicians and health care workers and may only be used under the supervision of a physician. This device will not be sold to the general public.	For posterior capsulotomy and iridotomy, the indications for use are equivalent.

Table 3. Subject to Predicate Device Comparison Table – Technical Characteristics

Attribute	Subject Device	Primary Predicate Device (K212630)	Primary Reference Device (K042139)	Equivalency Analysis and Discussion
Device name	VISULAS yag	Ellex YAG Laser (Ultra Q, Ultra Q Reflex)	VISULAS YAG III	-
Manufacturer	Carl Zeiss Meditec AG	Ellex Medical Pty Ltd	Carl Zeiss Meditec AG	-
510(k)	K230350	K212630	K042139	-
Classification Product Code	HQF	HQF	GEX	Substantially Equivalent. Though the reference device was cleared under product code 'GEX' in regulation 21 CFR 878.4810, current devices with these indications for use and technological characteristics are classified under product code 'HQF' ("Laser, Ophthalmic") in regulation 21 CFR 886.4390 ("Ophthalmic laser").
Regulation #	21CFR886.4390 Ophthalmic Laser	21CFR886.4390 Ophthalmic Laser	21CFR878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	Substantially Equivalent.
Application	Ophthalmic surgery	Ophthalmic surgery	Ophthalmic surgery	Substantially Equivalent.
Combination Device	No	No	No	Substantially Equivalent.
Patient Population	Adults	No restrictions given in the operator manual	Adults	Substantially Equivalent.

Attribute	Subject Device	Primary Predicate Device (K212630)	Primary Reference Device (K042139)	Equivalency Analysis and Discussion
User Interface	Graphical user interface, TouchControl panel, foot switch, laser slit lamp	Remote control, console, footswitch pedal, laser slit lamp	Graphical user interface, control, foot switch, laser slit lamp	Substantially Equivalent.
Optic Principle	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser	Substantially Equivalent.
Wavelength of Treatment Beam	1064 nm	1064 nm	1064 nm	Substantially Equivalent.
Laser Class in Accordance with IEC 60825-1	4	3B	4	Substantially Equivalent. The subject device utilizes standard IEC 60825-1 which contains safety requirements that shall be followed to allow equally safe usage of the lasers in humans.
Light Hazard Classification According to ISO 15004-2	Group 2	Group 2	Group 2	Substantially Equivalent.
Mode of Laser Beam	Super Gaussian	Not specified in the operator manual	Super Gaussian	Substantially Equivalent.
Pulse Length	< 4 ns	< 4 ns	< 4 ns (typically 2 ns to 3 ns)	Substantially Equivalent.
Pulse Mode 1 (Single Pulse)	9.0 mJ to 13.0 mJ, at max. 2.5 Hz	0.3 mJ to 10.0 mJ single pulse. Max. 3.0 Hz	9.0 mJ to 13.0 mJ, 2.5 Hz (5 shots/ 2s)	Substantially Equivalent.
Pulse Mode 2 (Double Pulse)	18.0 mJ to 28.0 mJ, at max. 1 Hz (burst frequency 33 kHz)	Not specified. Max. 1.8 Hz	18.0 mJ to 28.0 mJ, 1 Hz (1 shots/ 1s) (burst frequency 33 kHz)	Substantially Equivalent.

Attribute	Subject Device	Primary Predicate Device (K212630)	Primary Reference Device (K042139)	Equivalency Analysis and Discussion
Pulse Mode 3 (Triple Pulse)	29.0 mJ to 45.0 mJ, at max. 1 Hz (2 shots/ 2s) (burst frequency 33 kHz)	Not specified. Max. 1.6 Hz	29.0 mJ to 45.0 mJ, 0.5 Hz (1 shots/ 2s) (burst frequency 33 kHz)	Substantially Equivalent.
Energy Attenuation	2/4/6/8/10/12/14/16/20/24/28/32/36/40/42/48/56/60/64/70/80/100 %	Not specified.	2/4/6/8/10/12/14/16/20/24/28/32/36/40/42/48/56/60/64/70/80/100 %	Substantially Equivalent.
Applied Energy	Resulting from pulse mode and attenuation: 0.18 mJ – 13.0 mJ single pulse in 22 steps. Maximum energy that can be delivered during clinical use is 45 mJ.	0.3 mJ to 10.0 mJ single pulse. Continuously variable. Maximum energy that can be selected during clinical use is 30 mJ.	Average from the last five shots, continuously updated during the session. Maximum energy output is 10 mJ.	Substantially Equivalent.
Focus diameter	6.5 µm ± 20%	8 µm (Full Width Half Maximum)	10 µm in air	Substantially Equivalent. The subject device has refined the measuring method of the predicate device. The focus diameter for both lasers are identical.
Angle of Exit Aperture (Convergence)	14° (round angle)	16° (full cone angle)	16° (round angle)	Substantially Equivalent. The subject device has refined the measuring method of the predicate

Attribute	Subject Device	Primary Predicate Device (K212630)	Primary Reference Device (K042139)	Equivalency Analysis and Discussion
				device. The convergence angles are identical.
Aiming Beam	Diode Wavelength: 660 nm to 680 nm Power: max. 150 µW at the cornea (Class I in accordance with IEC 60825-1) Four-point aiming beam which is switchable to 2-point aiming beam	Laser diode-pumped Wavelength: Ultra Q: 635 nm Ultra Q Reflex: 635 nm or 515 nm Class II in accordance to IEC 60825-1 2-point aiming beam	Diode Wavelength: 660 nm to 680 nm Power: max. 150 µW at the cornea (Class I in accordance with IEC 60825-1) Four-point aiming beam	Substantially Equivalent.
Nominal Ocular Hazard Distance (NOHD)	4 m	6.1 m	2 m	The NOHD differs due to differences in the design. This difference does not impact the safety or performance of the subject device.
Rated Voltage; Frequency	100 V to 240 V (±10 %); 50 /60 Hz	100 V to 240 VAC; 50/60 Hz	100 V to 240 V ±10 %; 50 Hz/60 Hz	Substantially Equivalent.
Focus Shift between Aiming Beam and Therapy Beam	0/150/225/300 µm anterior and posterior adjustable Tolerance: ±25 µm	Ultra Q: Posterior only, continuously variable with detents at 100, 250 and 350 µm Ultra Q Reflex: Anterior (A) & posterior (P), continuously variable with detents at 0, 100, 200, 300, 400 and 500 µm	0/150 µm anterior and posterior adjustable Tolerance: ±25 µm	Substantially Equivalent.
Illumination	LED 5.6 V, 2 W	12 V pre-centered halogen	Halogen lamp 12 V, 30 W	Different.

Attribute	Subject Device	Primary Predicate Device (K212630)	Primary Reference Device (K042139)	Equivalency Analysis and Discussion
	Brightness continuously adjustable		Brightness continuously adjustable	
Illumination Orientation	Non-coaxial	Ultra Q: non-coaxial Ultra Q Reflex: coaxial	Non-coaxial	Substantially Equivalent.
Illumination Angle	0°/±45°/90°	180° at horizontal plane (90° for right / left)	0°/±45°/90°	Substantially Equivalent.
Slit Width	0 mm to 14 mm (continuously adjustable)	0 - 12 mm	0 mm to 14 mm (continuously adjustable)	Substantially Equivalent.
Slit Height	1/3/5/9/14 mm	0.5, 5.0, 8.0 & 12.0 or 0.5, 3.0, 8.0 & 12.0 mm	1/3/5/9/14 mm	Substantially Equivalent.
Magnification	8x/12x/20x	Ultra Q: Standard: 10×, 16×, 28× Accessory: 6×, 10×, 16×, 28×, 45× Ultra Q Reflex Standard: 10×, 16×, 25× Accessory: 6×, 10×, 16×, 28×, 45×	5x/8x/12x/20x/32x	Substantially Equivalent.

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications. ZEISS demonstrated non-clinical equivalency between the subject device, VISULAS yag, and the predicate device, VISULAS YAG III.

VISULAS yag is not intended for sterilization and no shelf life is specified for VISULAS yag. Therefore, no testing was conducted on VISULAS yag concerning sterilization and shelf life.

Biocompatibility testing was performed on the appropriate components of the subject device. The testing performed aligns with current recognized standards and meets or exceeds testing performed on VISULAS YAG III. Biocompatibility testing demonstrated equivalency between VISULAS yag and VISUALAS yag III.

Software verification and validation testing were conducted, and documentation was provided as recommended in accordance with IEC 62304. There have been no changes in level of concern or software architecture. All testing passed.

EMC and electrical safety are used in comparable standards to the predicate device and the relevant product standards given by the product indication and performance. Electrical safety and EMC testing were performed based on the ILAC-Scheme to include all national deviations for VISULAS yag. All testing passed.

No additional safety or performance concerns have been raised during development or device testing.

8. CONCLUSION

The indications for use are identical to the indications for use of the predicate device; and therefore, are deemed to be substantially equivalent.

The technological characteristics and risk profile of the subject device are equivalent to the predicate device; and therefore, are deemed to be substantially equivalent.

Testing methods are equivalent to those of the predicate device; and therefore, are deemed to be substantially equivalent.

Therefore, the subject device meets the requirements for substantial equivalence as compared to the proposed predicate device.