September 6, 2024

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

Re: K233911
Trade/Device Name: VISULAS combi
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 2, 2024
Received: August 5, 2024

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 (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
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)*
K233911

Device Name
VISULAS combi

Indications for Use *(Describe)*
VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including:
• Photocoagulation of the retina
• Trabeculoplasty
• Iridotomy
• Posterior capsulotomy
• Posterior membranectomy
This device is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for VISULAS combi is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena Germany
Contact	Dr. Ling Ren Regulatory Affairs Manager Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 | 07745 Jena, Germany Phone: +49 7364 2062845 E-mail: tanesha.bland@zeiss.com (preferred)
Primary Correspondent	Tanesha Bland Sr. Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 Phone: (925) 216-7963 | Fax: (925) 557-4259 E-mail: tanesha.bland@zeiss.com (preferred)
Date Prepared:	August 30, 2024

2. SUBJECT DEVICE

Device Trade Name:	VISULAS combi
510(k) number:	K233911
Classification:	21CFR886.4390 laser, Ophthalmic
Regulatory Class:	II
Product Code:	HQF

3. PREDICATE DEVICE

Table 1. Primary Predicate Device- VISULAS green

Predicate Device:	VISULAS green
510(k) Number:	K232051
Classification:	21CFR886.4390 Laser, Ophthalmic
Regulatory Class:	II
Product Code:	HQF

Table 2. Secondary Predicate Device- VISULAS yag

Predicate Device:	VISULAS yag
510(k) Number:	K230350
Classification:	21CFR886.4390 Laser, Ophthalmic
Regulatory Class:	II
Product Code:	HQF

4. DEVICE DESCRIPTION

VISULAS combi is an ophthalmic laser used for standard photocoagulation treatments of ocular tissue with 532 nm wavelength and standard photodisruption treatments of ocular tissues at a wavelength of 1064 nm. VISULAS combi is operated in the following treatment modes:

- single-spot mode (software license VERTE)
- multi-spot mode (software license VITE)
- YAG disruption mode (software license YAG).

VISULAS combi consists of a laser console, touch control panel, optional laser light applicators such as laser slit lamp or laser indirect ophthalmoscope, foot switch and instrument table. The device can also be used with various accessories, such as SL Imaging Solution, contact lenses or Applanation Tonometer.

5. INDICATIONS FOR USE

VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including

- Photocoagulation of the retina
- Trabeculoplasty
- Iridotomy
- Posterior capsulotomy
- Posterior membranectomy

This device is Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

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

	VISULAS combi	**VISULAS green**
K number	**Subject Device**	**K232051**
Legal manufacturer	**Carl Zeiss Meditec AG**	**Carl Zeiss Meditec AG**
Indications for Use Statement	VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including • Photocoagulation of the retina • Trabeculoplasty • Iridotomy • Posterior capsulotomy • Posterior membranectomy	VISULAS green is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye, including • Photocoagulation of the retina • Trabeculoplasty • Iridotomy
General Laser Specifications		
Laser type	solid state laser, frequency-doubled	solid state laser, frequency-doubled
Wavelength	532 nm	532 nm
Power (cw laser)	50 to 1500 mW	50 to 1500 mW
Length of pulse	10 – 2500 ms and cw	10 – 2500 ms and cw
Repeat mode	yes	yes
Laser spot size settings	50 µm to 1000 µm	50 µm to 1000 µm
Aiming beam	620 – 650 nm	620 – 650 nm
Types of laser applicators	LSL, laser endoprobes, LIO	LSL, laser endoprobes, LIO
Multi-spot treatment mode	yes	yes
Increments of power	50-200 mW (10 mW steps), 200-500 mW (20 mW steps), 500-1500 mW (50 mW steps)	50-200 mW (10 mW steps), 200-500 mW (20 mW steps), 500-1500 mW (50 mW steps)
Laser spot size setting	Continuously adjustable from 50 µm to 1000 µm	Continuously adjustable from 50 µm to 1000 µm
Conditions of Use		
Site in the body	eye	eye
Principle of operation	Photocoagulation of ocular tissue	Photocoagulation of ocular tissue

Table 2. Subject to Primary Predicate Device Comparison Table – Laser Slit Lamp
The Laser Slit Lamp (LSL) is an optional component of the VISULAS laser.

	LSL green combi	**LSL green comfort**
K number	**Component of subject device VISULAS combi**	**Component of predicate device VISULAS green (K232051)**
Legal manufacturer	**Carl Zeiss Meditec AG**	**Carl Zeiss Meditec AG**
Design		
Slit lamp type	ZEISS type	ZEISS type
Tube system	Parallel or convergent	Parallel or convergent
Power supply	Via laser console	Via laser console
Specifications		
Slit width	0 mm to 14 mm (continuously)	0 mm to 14 mm (continuously)
Slit length	1/3/5/9/14 mm	1/3/5/9/14 mm
Slit image rotation	0°, ±45°, 90°	0°, ±45°, 90°
Magnification	5 magnifications, in steps of 5x, 8x, 12x, 20x, 32x	5 magnifications, in steps of 5x, 8x, 12x, 20x, 32x
Light source	LED illumination, continuously adjustable brightness	LED illumination, continuously adjustable brightness
Micromanipulator	yes	yes

The subject device VISULAS combi and the primary predicate device VISULAS green are both intended as ophthalmic lasers for photocoagulation. For photocoagulation treatments, the indications for use are within the same intended use as the predicate device and do not raise different questions of safety and effectiveness.
The subject device VISULAS combi and the primary predicate laser system share the same fundamental parameters and the same fundamental principle of operation:

Photocoagulation: Continuous wave operation in which thermal energy created by the absorption of the laser energy by the ocular tissue is causing coagulation.

For photocoagulation treatments, the subject device VISULAS combi is substantially equivalent to the primary predicate laser system presented in the 510(k) premarket notification in terms of indications for use and technological characteristics. Differences between subject device and predicate devices do not raise any new issues of safety or effectiveness.

Table 3. Subject to Secondary Predicate Device Comparison Table – Indications for Use

	VISULAS combi	**VISULAS yag**
K number	**Subject Device**	**K230350**
Legal manufacturer	**Carl Zeiss Meditec AG**	**Carl Zeiss Meditec AG**
Indications for Use Statement	VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including • Photocoagulation of the retina • Trabeculoplasty	VISULAS yag is intended for use in photodisrupting ocular tissues in the treatment of diseases of the eye, including • Posterior capsulotomy • Iridotomy • Posterior membranectomy

	• Iridotomy • Posterior capsulotomy • Posterior membranectomy	
General Laser Specifications		
Optic principle	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser
Wavelength of treatment beam	1064 nm	1064 nm
Pulse duration	< 4 ns	< 4 ns
Laser class in accordance with IEC 60825-1	4	4
Light hazard classification according to ISO 15004-2	Group 2	Group 2
Pulse Mode 1 (Single Pulse)	9.0 mJ to 13.0 mJ, at max. 2.5 Hz	9.0 mJ to 13.0 mJ, at max. 2.5 Hz
Pulse Mode 2 (Double Pulse)	18.0 mJ to 28.0 mJ, at max. 1 Hz (burst frequency 33 kHz)	18.0 mJ to 28.0 mJ, at max. 1 Hz (burst frequency 33 kHz)
Pulse Mode 3 (Triple Pulse)	29.0 mJ to 45.0 mJ, at max. 1 Hz (2 shots/ 2s) (burst frequency 33 kHz)	29.0 mJ to 45.0 mJ, at max. 1 Hz (2 shots/ 2s) (burst frequency 33 kHz)
Conditions of Use		
Site in the body	eye	eye
Principle of operation	Photodisruption of ocular tissue	Photodisruption of ocular tissue

Table 4. Subject to Reference Device Comparison Table – Laser Slit Lamp
The Laser Slit Lamp (LSL) is an optional component of the VISULAS laser.

	LSL green combi	**LSL yag**
K number	**Component of subject device VISULAS combi**	**Component of reference device VISULAS yag (K230350)**
Legal manufacturer	**Carl Zeiss Meditec AG**	**Carl Zeiss Meditec AG**
Design		
Laser beam guidance	Free beam arrangement in the head of the laser slit lamp	Free beam arrangement in the head of the laser slit lamp
Energy attenuation	22 levels: 2/4/6/8/10/12/14/16/20/24/ 28/32/36/40/42/48/56/60/6 4/70/80/100 %	22 levels: 2/4/6/8/10/12/14/16/20/24/ 28/32/36/40/42/48/56/60/6 4/70/80/100 %
YAG focus diameter	6.5 µm ± 20% in air	6.5 µm ± 20% in air
YAG laser beam divergence	14° ± 20% (round angle)	14° ± 20% (round angle)
YAG aiming beam	Diode, 2-point / 4-point (switchable) 660 nm to 680 nm, max. 150 µm at the cornea (class 1 in accordance with IEC 60825-1)	Diode, 2-point / 4-point (switchable) 660 nm to 680 nm, max. 150 µm at the cornea (class 1 in accordance with IEC 60825-1)
Focus shift between aiming and therapy beam	0/150/225/300 µm, toggle between anterior and posterior	0/150/225/300 µm, toggle between anterior and posterior
Nominal Ocular Hazard Distance (NOHD) of YAG laser	4 m	4 m

The subject device VISULAS combi and the secondary predicate device VISULAS yag are both intended as ophthalmic lasers for photodisruption. For photodisruption treatments, the indications for use are within the same intended use as the reference device and do not raise different questions of safety and effectiveness.
The subject device VISULAS combi and the reference laser system share the same fundamental parameters and the same fundamental principle of operation:

> Photodisruption: At the focus point of the laser beam pressure and temperature are very high to result in the formation of a laser-induced plasma allowing tissue photodisruption to take place. As the plasma expands, it cools down rapidly; hence, the thermal effect on adjacent tissue is very low. The mechanical stress to adjacent tissue due to the shock wave accompanying the photodisruption expansion of the plasma results in an incisional effect.

For photoisruption treatments, the subject device VISULAS combi is substantially equivalent to the secondary laser system presented in the 510(k) premarket notification in terms of indications for use and technological characteristics. Differences between subject device and reference devices do not raise any new issues of safety or effectiveness.

7. SUMMARY OF STUDIES

Biocompatibility Testing

ZEISS conducted biocompatibility testing on patient-contacting accessories in accordance with ISO 10993-1. The evaluations addressed cytotoxicity, sensitization, and irritation, aligning with the recommendations delineated in the FDA guidance document "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process". The testing performed aligns with current recognized standards and meets or exceeds testing performed on the predicate device. Biocompatibility testing demonstrated equivalency between the subject device and the predicate device.

Laser safety, electrical safety and electromagnetic compatibility (EMC)

VISULAS combi was evaluated against the following requirements and was found to comply with:

- ANSI/AAMI ES60601-1:2005/(R) 2012
- ANSI Z80.36-2016
- IEC 60601-1-2:2014
- IEC 60825-1:2007
- IEC 60601-2-22:2012
- IEC 62133: 2012
- IEC 60601-4-2

Software Verification and Validation Testing

The software of this device is considered to have an Enhanced Documentation Level. Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification and validation of VISULAS combi demonstrated that the product works as designed.

Bench 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 and the predicate device.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

The VISULAS combi is substantially equivalent to the primary predicate device VISULAS green (K232051) and the secondary predicate device VISULA yag (K230350).

The VISULAS combi is similar in technological characteristics, performance, principles of operation, and has identical indications for use as the primary predicate device and the secondary predicate device. Any differences between the proposed device and the predicate devices do not raise any new issues.

Results of the non-clinical performance testing support a determination of substantial equivalence between the subject device and the predicate devices for the proposed intended use.

Thus, the VISULAS combi meets the requirements for substantial equivalence as compared to the predicate devices, VISULAS green (K232051) and VISULAS yag (K230350).