October 24, 2023

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

Re: K232051
Trade/Device Name: VISULAS green
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 26, 2023
Received: August 28, 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 (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.

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,

Elvin Y. Ng -S

Elvin Ng
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)*
K232051

Device Name
VISULAS green

Indications for Use *(Describe)*
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

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.

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

1. SUBMITTER

Applicant:	Carl Zeiss Meditec, Inc. 5300 Central Parkway Dublin, CA USA
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Date Prepared:	October 12, 2023

2. SUBJECT DEVICE

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

3. PREDICATE DEVICE

Predicate Device:	VISULAS green
510(k) Number:	K181682
Classification:	21CFR886.4390 Optic Ophthalmic laser
Regulatory Class:	II
Product Code:	HQF

4. DEVICE DESCRIPTION

VISULAS green is an ophthalmic laser used for standard photocoagulation treatments of ocular tissue with 532 nm wavelength. VISULAS green is operated in single-spot mode or in multi-spot mode.

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

- Photocoagulation of the retina
- Trabeculoplasty
- Iridotomy

This device is Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

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

	VISULAS green	**VISULAS green**
K number	**K232051**	**K181682**
Legal manufacturer	**Carl Zeiss Meditec AG**	**Carl Zeiss Meditec AG**
Indications for Use Statement	**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**	**The VISULAS green is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye, including** **-Photocoagulation of the retina** **-Trabeculoplasty for treatment of glaucoma** **-Iridotomy for treatment of glaucoma**
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, VISULINK 532/U, 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)	50-100 mW (10 mW steps), 100-1500 mW (50 mW steps)
Laser spot size settings	Continuously adjustable from 50 µm to 1000 µm	50 µm,100 µm, 200 µm, 300 µm, 500 µm, 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 Predicate Device Comparison Table – Laser Slit Lamps

The Laser Slit Lamps (LSL) are optional components of the subject device VISULAS green (K232051) and the predicate device VISULAS green (K181682).

	LSL green classic, LSL green comfort	**LSL green classic, LSL green comfort**
K number	**Component of subject device VISULAS green (K232051)**	**Component of predicate device VISULAS green (K181682)**
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)	LSL green classic: 0.2 mm / 0.6 mm / 1.6 mm / 4.4 mm / 15.0 mm LSL green comfort: 0 mm to 14 mm (continuously)
Slit length	1/3/5/9/14 mm	LSL green classic: 1/3/5/7/10/12/14/15 mm LSL green comfort: 1/3/5/9/14 mm
Slit image rotation	0°, ±45°, 90°	0°, ±45°, 90°
Magnification	LSL green classic: 3 magnifications in steps of 8x, 12x, 20x LSL green comfort: 5 magnifications, in steps of 5x, 8x, 12x, 20x, 32x	LSL green classic: 3 magnifications in steps of 8x, 12x, 20x LSL green comfort: 5 magnifications, in steps of 5x, 8x, 12x, 20x, 32x
Light source	LED illumination, continuously adjustable brightness	Halogen 12V/30W, brightness continuously adjustable
Micromanipulator	LSL green classic: no LSL green comfort: yes	LSL green classic: no LSL green comfort: yes

The VISULAS green and predicate devices are both intended as ophthalmic lasers for photocoagulation. The indications for use are within the same intended use as the predicate devices and do not raise different questions of safety and effectiveness.

The primary differences between the subject device, VISULAS green (K232051), and the predicate device, VISULAS green (K181682), are listed in the following table with corresponding justification as to why the changes do not affect the safety and effectiveness of the subject device.

Table 3. Differences between the subject device and the predicate device and justification of no impact on safety and effectiveness

Differences between the subject device and the predicate device	Justification of no impact on safety and effectiveness
The illumination source of the Laser Slit Lamps is changed from halogen lamp to LED.	The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
The slit width of LSL green classic is changed from available in 5 steps to continuously adjustable 0 – 14 mm.	The slit width of LSL green classic is now the same as that of LSL green comfort. The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
The slit length of LSL green classic is changed from available in 8 steps to available in 5 steps.	The slit length of LSL green classic is now the same as that of LSL green comfort. The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
New color scheme of the outer parts is applied.	The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
The guidelines of ZEISS User Interface are applied to the software.	The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
The Instructions for Use is updated to reflect the changes and to adapt to the editorial scheme.	The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.
Changes to tackle obsolescence issues.	The subject device went through the same Verification and Validation Process as the predicate device and passed the applicable testing.

The VISULAS green subject device and the predicate laser systems have minor parameter differences but share 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.

The subject VISULAS green is substantially equivalent to the predicate laser systems 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.

7. SUMMARY OF STUDIES

Biocompatibility Testing

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 the predicate device. Biocompatibility testing demonstrated equivalency between the subject device and the predicate device.

Laser safety, electrical safety and electromagnetic compatibility (EMC)

VISULAS green 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

Software Verification and Validation Testing

The software of this device is considered as a “Major” level of concern. 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 green 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 green is substantially equivalent to the predicate device, VISULAS green (K181682).

The VISULAS green is similar in technological characteristics, performance, principles of operation, and has identical indications for use as the predicate device. Any differences between the proposed device and the predicate devices do not raise any new issues of safety or effectiveness. Thus, the VISULAS green is substantially equivalent to the predicate devices.