April 13, 2018

Carl Zeiss Meditec, Inc.
Todd Otani
Sr. Clinical Research Scientist
5160 Hacienda Drive
Dublin, CA 94568

Re: K173371
Trade/Device Name: VisuMax Femtosecond Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF, HNO
Dated: March 13, 2018
Received: March 14, 2018

Dear Todd Otani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173371

Device Name
VisuMax Femtosecond Laser

Indications for Use *(Describe)*

The VisuMax Femtosecond Laser is cleared for the following indications for use:

• In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
• In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
• In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty;
• In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting;
• In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE, CONTACT PERSON AND DATE SUMMARY PREPARED

a. Applicant: Carl Zeiss Meditec AG
Goeschwitzer Strasse 51-52
7740 Jena
Germany

b. Contact Person: Todd Otani, O.D.
Carl Zeiss Meditec, Inc.
Zeiss Group
5160 Hacienda Drive
Dublin, California 94568, USA
t.otani@zeiss.com
Tel: (925) 557-4513
Fax: (925) 557-4259

c. Date: 2018-04-12

NAME OF DEVICE, TRADE NAME AND CLASSIFICATION

Trade/Proprietary Name: VisuMax Femtosecond Laser

Common/Usual Name: Femtosecond Laser

Classification Name: Laser, Ophthalmic
Keratome, AC-powered

Classification Code(s): 21 CFR 886.4390; 79 HQF
21 CFR 886.4370; 79 HNO

PREDICATE DEVICE(S)

PREDICATE DEVICE	MANUFACTURER	510(K) CLEARANCE
VisuMax Laser Keratome	Carl Zeiss Meditec	K100253
WaveLight FS200	Alcon Novartis	K141476
IntraLase iFS Laser	Abbott Medical Optics	K141852

DEVICE DESCRIPTION

The VisuMax Femtosecond Laser is an ophthalmic surgical femtosecond laser intended for use in patients requiring corneal incisions. The cutting action of the VisuMax laser is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vacuum.

INDICATIONS FOR USE

The VisuMax Femtosecond Laser is cleared for the following indications for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty;
- In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject VisuMax Femtosecond Laser is essentially the same device as the VisuMax Laser Keratome predicate device (K100253) with the addition of software modifications made to enable the expansion of the indications for use and minor modifications made to meet manufacturability and service requirements.

The VisuMax subject and the predicate laser systems share the same operating principle and mode of operation whereby the creation of tissue resections are produced by scanned patterns of femtosecond laser micro-photodisruptions in cornea.

The subject VisuMax Femtosecond Laser is substantially equivalent to the predicate laser systems presented in this 510(k) premarket notification in terms of indications for use, technological characteristics and fundamental scientific technology. No changes to the VisuMax Femtosecond Laser system specifications, system design, or hardware control system were made to implement the expanded indication for use. The laser parameters in the subject device are identical to those of the VisuMax predicate device (K100253).

As seen in the Technological Comparison table below, the subject device is identical to the primary predicate device with the exception of the software modifications implemented to enable the new indication for use. Differences between the VisuMax and the secondary predicate devices are limited to the maximum repetition rate and the maximum pulse energy and do not represent a difference in the fundamental technology of this device. Testing confirmed that the VisuMax performance is equivalent to that of the predicate devices.

Software modifications implemented to support the expanded indications (i.e. creation of tunnel cuts for the placement of corneal ring segments), allow the VisuMax to produce tunnel cuts equivalent to those produced by predicate devices K141852 and K141476, and to allow the user based tunnel cut parameter selection on the graphical user interface (GUI).

The tunnel cutting functionality was shown to be substantially equivalent to the functionality of the predicate devices through a comparison of the relevant technical specifications, characteristics and features for the corneal ring segment cutting procedure.

TECHNOLOGICAL COMPARISON
VISUMAX FEMTOSECOND LASER & PREDICATE DEVICES

510(k) clearance	K173371 (proposed)	K100253 (primary predicate)	K141852 (secondary predicate)	K141476 (secondary predicate)
Device Name	VisuMax Femtosecond Laser	VisuMax Laser Keratome	iFS Laser System	WaveLight FS200
Manufacturer	Carl Zeiss Meditec	Carl Zeiss Meditec	Abbott Medical Optics	Alcon Novartis
Indications for Use	The VisuMax Femtosecond Laser is indicated for the following: • In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea; • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea; • In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; • In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.	The VisuMax Laser Keratome is indicated for the following: • In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea; • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea; • In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; • In the creation of a cut/incision for penetrating keratoplasty and corneal harvesting	The iFS Laser System is an ophthalmic surgical laser designed for use as an ophthalmic surgical laser indicated for use as follows: • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments • In lamellar keratoplasty and corneal harvesting • In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea • In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty • In the creation of lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of penetrating cut/incision for penetrating keratoplasty.	The WaveLight FS200 Laser System is an ophthalmic surgical laser indicated for use: • In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea. • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments. • In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty. • In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting. • In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea. • In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/incisions in the cornea.
Operating principle	Femtosecond laser photodisruption	Femtosecond laser photodisruption	Femtosecond laser photodisruption	Femtosecond laser photodisruption
Mechanism of action	Cutting surfaces created by scanned patterns of femtosecond laser micro-photodisruptions in cornea.	Cutting surfaces created by scanned patterns of femtosecond laser micro-photodisruptions in cornea.	Cutting surfaces created by scanned patterns of femtosecond laser micro-photodisruptions in cornea.	Cutting surfaces created by scanned patterns of femtosecond laser micro-photodisruptions in cornea.
Wavelength	1043 nm	1043 nm	1053 nm	1030 nm
Repetition rate	500 kHz	500 kHz	60 kHz	200 kHz
Pulse energy, max	0.375 uJ	0.375 uJ	2.50 uJ	2.40 uJ

PERFORMANCE DATA

Performance data supporting substantial equivalence of the modified VisuMax Femtosecond Laser and the predicate devices included the following:

- The accuracy and repeatability of corneal tunnel lateral dimensions were verified using a non-contact optical technique in *ex vivo* corneas. Tunnel cuts were made in a series of corneal models using a range of cut parameters spanning the VisuMax tunnel cut parameter ranges. Test acceptance criteria for all cut length dimension and cut angular dimensions were met.

- The accuracy and repeatability of corneal tunnel depth dimensions were verified using a non-contact optical technique in a corneal model material. Cut depth measurements in the model material validated by comparing depth measurements made in both ex vivo corneas and the model material. Tunnel cuts were made in a series of corneal models using a range of cut parameters spanning the VisuMax tunnel cut parameter ranges. Test acceptance criteria for all cut depth dimensions were met.

- Cut quality for the tunnel cuts was evaluated in *ex vivo* corneas for ease of tissue separation following the creation of the access and tunnel cuts. All corneas tested in this manner were judged to be of good cut quality, meeting the performance test acceptance criteria.

In summary, performance testing demonstrated that the tunnel cut features for the expanded indications for use by the VisuMax subject device are equivalent to the predicate devices in terms of cut dimension accuracy, cut repeatability and cut quality.

The VisuMax Femtosecond Laser also underwent medical electrical equipment testing and was found to be in compliance with the following applicable international safety standards:

- IEC 60601-1 -- Medical Electric equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 -- Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1-6 -- Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
- IEC 60601-2-22 -- Medical Electrical Equipment, Part 2-22: Particular Requirements for basic Safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1 -- Safety of Laser Products, Part 1: Equipment Classification and Requirements
- IEC 62304 -- Medical Device Software - Software Life Cycle Processes
- IEC 62366 -- Medical devices - Application of usability engineering to medical devices

SOFTWARE VERIFICATION AND VALIDATION

The software for the VisuMax Femtosecond Laser is considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification and validation testing of the VisuMax software has been performed for both the system software and all associated software modules. The software verification and validation testing results demonstrate that the VisuMax Femtosecond Laser meets all requirements for performance, accuracy, functionality and safety for the modifications proposed in this 510(k) premarket notification.

CONCLUSION

The purpose of this 510(k) Premarket Notification is to obtain clearance for an additional new indication for use for the creation of tunnel cuts for the placement of corneal ring segments for the VisuMax Femtosecond Laser. The VisuMax Femtosecond Laser is essentially the same as the predicate VisuMax Laser Keratome, with software modifications that enable the new indication for use. These modifications result in a VisuMax Femtosecond Laser that is substantially equivalent to the other predicate devices included in this 510(k) Premarket Notification. The supportive information provided in this 510(k) Premarket Notification provides reasonable assurance that the VisuMax Femtosecond Laser is safe and effective for its intended use and that it is substantially equivalent to the legally marketed predicate devices.