July 31, 2023

Carl Zeiss Meditec AG
% Aditya Rao
Regulatory Affairs Specialist- USA
Carl Zeiss Meditec Inc
5300 Central Parkway
Dublin, California 94568

Re: K230858
Trade/Device Name: Quatera 700
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE
Dated: June 26, 2023
Received: June 27, 2023

Dear Aditya Rao:

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,

Elvin Y. Ng -S

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)*
K230858

Device Name
QUATERA 700

Indications for Use *(Describe)*
QUATERA System (QUATERA 700) is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. In combination with various required components and accessories, the device is designed for use in anterior segment surgery. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation and anterior vitrectomy.
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.

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

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In accordance with 21 CFR 807.92 the 510(k) Summary for the QUATERA 700 is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwizer Strasse 51-52 D-07745 Jena Germany
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Date Prepared:	July 31, 2023

2. DEVICE

Device Trade Name:	QUATERA 700 (Software Version 1.1.4)
Classification:	21CFR886.4670 Phacofragmentation System
Regulatory Class:	II
Product Code:	HQC, HQE

3. PREDICATE DEVICE

Predicate Device:	QUATERA 700 (Software Version 1.1.0)
Classification:	21CFR886.4670 Phacofragmentation System
Regulatory Class:	II
Product Code:	HQC, HQE

4. DEVICE DESCRIPTION

QUATERA 700 is a mobile phacoemulsification system designed for use in the ophthalmic surgical operating rooms during surgery of the anterior eye segment. When QUATERA 700 is used with compatible components and accessories, the system will perform the following surgical procedures: irrigation and/or aspiration, phacoemulsification of crystalline lens, anterior vitrectomy, and bipolar coagulation.

QUATERA 700 has fluidic, ultrasound and pneumatic modules for emulsification and aspiration of the cataractous lens from eye and maintain the pressure and volume of the eye intraoperatively. The required values are pre-set via a Graphical User Interface and controlled directly by the surgeon using the Foot Control Panel of the device and delivered in the eye via a range of accessories. The systems control mechanism verifies the output values and the pre-set values.

QUATERA 700 has the following functions:
• Irrigation and Aspiration
• Ultrasound Capability
• Diathermy
• Anterior Vitrectomy
• Reflux

QUATERA 700 is intended to be used within a clinic(s)/hospital(s)/surgical practice network.

5. INTENDED USE/INDICATIONS FOR USE

The intended use statement for the subject device is as follows:

QUATERA 700 is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. The device is designed for use in anterior segment surgery. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/ aspiration, bipolar coagulation and anterior vitrectomy.

The Indications for Use (IFU) statement for the subject device is as follows:

QUATERA System (QUATERA 700) is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. In combination with various required components and accessories, the device is designed for use in anterior segment surgery. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation and anterior vitrectomy.

This device is for Prescription Use (Rx) only.

6. SUBSTANTIAL EQUIVALENCE

6.1. Primary Predicate

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

Subject Device	Predicate Device (K212241)	Equivalency Analysis
QUATERA 700 is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The device is designed for use in anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/ aspiration, bipolar coagulation, anterior vitrectomy, viscous fluid injection/ removal and air/fluid exchange operations.	QUATERA 700 is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The device is designed for use in anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/ aspiration, bipolar coagulation, anterior vitrectomy, viscous fluid injection/ removal and air/fluid exchange operations.	The indications for use are equivalent as basis of the medical context.

Table 2. Subject to Predicate Device Comparison Table – Technical Characteristics

Attribute	Subject Device	Primary Predicate Device (K212241)	Equivalency Analysis
Device name	QUATERA System (QUATERA 700 (SW V1.1.4))	QUATERA System (QUATERA 700 (SW V1.1.0))	N/A
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Identical
510(k)	**K230858**	**K212241**	N/A
Classification Product Code	HQC, HQE	HQC, HQE	Identical
Regulation #	21CFR886.4670	21CFR886.4670	Identical

Attribute	Subject Device	Primary Predicate Device (K212241)	Equivalency Analysis
	Phacofragmentation System	Phacofragmentation System	
Application	Ophthalmic Surgery	Ophthalmic Surgery	Identical
Combination Device	No	No	Identical
Patient Population	Adults	Adults	Identical
System Procedures	- Irrigation / Aspiration - Ultrasound - Diathermy - Anterior Vitrectomy	- Irrigation / Aspiration - Ultrasound - Diathermy - Anterior Vitrectomy	Identical
Accessories Provided Sterile	Yes	Yes	Identical
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
User Interface	Foot Control Panel, Graphical User Interface, Handpiece	Foot Control Panel, Graphical User Interface, Handpiece	Identical
IRRIGATION AND ASPIRATION			
Aspiration Pump Type	Flow Control & Vacuum ControlQuattro Pump	Flow Control & Vacuum Control Quattro Pump	Identical
Irrigation	Yes	Yes	Identical
Adjustable pump ramp	Yes	Yes	Identical
Continuous Irrigation	Yes	Yes	Identical
PHACOEMULSIFICATION			
Handpiece type	Piezoelectrical	Piezoelectrical	Identical
Range of frequency	40 kHz	40 kHz	Identical
Control	fixed or linear	fixed or linear	Identical
Tip stroke	up to 100µm	up to 100µm	Identical
Incision type Co-Mix	1.8mm	1.8mm	Identical
Pulse Mode/Duration	0 - 250 pps	0 - 250 pps	Identical
Phaco Tip Movement	longitudinal	longitudinal	Identical
DIATHERMY			
Operating Frequency	2 MHz (± 20%)	2 MHz (± 20%)	Identical
Foot Control Panel	Yes	Yes	Identical
ANTERIOR VITRECTOMY			
Pneumatic	Yes	Yes	Identical
Cutting mode	Back and Forth	Back and Forth	Identical
Cutter control	Linear or fixed	Linear or fixed	Identical
Single Cut	Yes	Yes	Identical

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Biocompatibility

QUATERA 700 is not intended to come into contact with the patient. The materials used for the device console are common and widely used for ophthalmic and similar applications without reported heath concerns. ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-12 standards have been followed for the accessories/ components, specifically regarding cytotoxicity, kligman maximization, and intracutaneous irritation and acute systemic toxicity testing.

Sterilization and Shelf Life

QUATERA 700 is a non-sterile system that has sterilized or reprocessed accessories. QUATERA 700 is not provided sterilized and is not intended to be sterilized during routine use.
Sterilization testing was performed on the appropriate components of the subject device. The testing aligns with current recognized standards and meets or exceeds testing performed for the predicate device.

Software Verification and Validation Testing

QUATERA 700 was tested according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005). In addition, the software testing also followed the Carl Zeiss Meditec internal software development procedure that follows the IEC 62304:2006+AC:2008 + AC:2015 – Medical device software –Software life cycle processes. Validation has been conducted according to IEC 62366. Testing passed.

Electromagnetic compatibility (EMC) and Electrical Safety Testing

Electrical safety and EMC testing were conducted in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-2 standards. Testing passed.

(Bench) Performance Testing

Additional laboratory (bench) performance tests have been conducted for QUATERA 700 to demonstrate efficacy, safety and substantial equivalence to predicate devices including:

-Testing to ensure compliance to IEC 80601-2-58 " Medical electrical equipment, Part 2: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery”
-Testing to ensure compliance to IEC 60601-2-2 " Medical electrical equipment Part 2:

Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories"

Animal/Clinical Performance Testing

Animal and Clinical testing was not conducted

8. REASONS FOR 510(k)

The subject device qualifies as a class II medical device and is therefore subject to a premarket notification.

Changes to K212241 include:

- Minor Software changes
- Minor changes to the QUATTRO CASSETTE that do not affect Sterilization and Biocompatibility
- Extension of shelf-life
- Changes to components and parts on the QUATERA 700 due to obsolescence reasons, minor improvements and small changes to the label.

9. CONCLUSION

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

The technological characteristics and risk profile of the subject device are equivalent to the predicate device.

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