April 19, 2022

Carl Zeiss Meditec AG
% Maria Golovina
Head of Regulatory Affairs - USA
Carl Zeiss Meditec Inc
5300 Central Parkway
Dublin, California 94568

Re: K212241
Trade/Device Name: QUATERA 700
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE
Dated: March 9, 2022
Received: March 10, 2022

Dear Maria Golovina:

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,

Anjana Jain, Ph.D.
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)*
K212241

Device Name
QUATERA 700

Indications for Use *(Describe)*
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.

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.***

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*"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."*

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
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Germany

Primary Correspondent Maria Golovina
Head of Regulatory Affairs - USA
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Date Prepared: April 18, 2022

## 2. SUBJECT DEVICE

| | |
|---|---|
| Device Trade Name: | QUATERA 700 |
| Classification: | 21CFR886.4670 Phacofragmentation System |
| Regulatory Class: | II |
| Product Code: | HQC, HQE |

## 3. PREDICATE DEVICE AND REFERENCE DEVICE

### 3.1. PREDICATE DEVICE

| | |
|---|---|
| Predicate Device: | EVA Ophthalmic Surgical System (K142877) |
| Classification: | 21 CFR 886.4670 Phacofragmentation System |
| Regulatory Class: | II |
| Product Code: | HQC, HQE, HQF |

### 3.2. REFERENCE DEVICE

| | |
|---|---|
| Predicate Device: | Visalis V500, Visalis S500 (K193376) |
| Classification: | 21 CFR 886.4670 Phacofragmentation System |
| Regulatory Class: | II |
| Product Code: | HQC |

## 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. INDICATIONS FOR USE

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 Prescription Use (Rx) only.

## 6. SUBSTANTIAL EQUIVALENCE TO PRIMARY PREDICATE

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

| **Subject Device** | **Primary Predicate Device (K142877)** | **Equivalency Analysis** |
|---|---|---|
| QUATERA 700 is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. In combination with various required components and | The EVA Ophthalmic Surgical System is indicated for both anterior segment (i.e. | The indications for use are equivalent as basis of the medical context. The different wording leads to |

| Subject Device | Primary Predicate Device (K142877) | Equivalency Analysis |
|---|---|---|
| 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. | phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery. | equivalent therapy options, however the indications provided by QUATERA 700 is clearer. |

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

| Attribute | Subject Device | Primary Predicate Device (K142877) | Equivalency Analysis |
|---|---|---|---|
| **Device name** | QUATERA System (QUATERA 700) | EVA Ophthalmic Surgical System | N/A |
| **Manufacturer** | Carl Zeiss Meditec AG | D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. | N/A |
| **510(k)** | K212241 | K142877 | N/A |
| **Classification Product Code** | HQC, HQE | HQC, HQE, HQF | Equivalent |
| **Regulation #** | 21CFR886.4670<br><br>Phacofragmentation System | 21CFR886.4670<br><br>Phacofragmentation System | Identical |
| **Application** | Ophthalmic Surgery | Ophthalmic Surgery | Identical |
| **Combination Device** | No | No | Identical |
| **Patient Population** | Adults | Adults | Identical |
| **System Procedures** | - Irrigation / Aspiration<br>- Ultrasound<br>- Diathermy<br>- Anterior Vitrectomy | - Irrigation / Aspiration<br>- Ultrasound<br>- Diathermy<br>- Vitrectomy<br>- Illumination<br>- Air tamponade<br>- Silicone tamponade<br>- Laser | Identical, narrower scope |
| **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 Control<br>Quattro Pump | Peristaltic | Different |
| **Irrigation** | Yes | Yes | Identical |

| Attribute | Subject Device | Primary Predicate Device (K142877) | Equivalency Analysis |
|---|---|---|---|
| **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 | 100 µm | Equivalent |
| **Incision type Co-Mix** | 1.8mm | 1.8 mm | Identical |
| **Pulse Mode/Duration** | 0 - 250 pps | 0 - 250 pps | Identical |
| **Phaco Tip Movement** | longitudinal | longitudinal | Identical |
| **DIATHERMY** | | | |
| **Operating Frequency** | 2 MHz (± 20%) | 1MHz ± 10% | Equivalent |
| **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**

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. Substantial equivalence was additionally demonstrated by using equivalent testing methods applied during testing of the subject device (such as biocompatibility, sterility, software, electrical safety, and software) as compared to the reference device. The totality of the performance data provided supports substantial equivalence and is summarized below.

*Biocompatibility & Animal Testing*

Biocompatibility assessments and testing for patient contacting components/accessories was performed in accordance with the following standards: ISO 10993-1, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, and ISO 10993-12, USP 34 <151>. Specifications regarding intracutaneous reactivity or acute ocular irritation tested in rabbits (ISO 10993-10), material mediated pyrogenicity tested in rabbits (USP 34 <151>), acute systemic cytotoxicity tested in mice (ISO 10993-11), kligman maximization (i.e., skin sensitization) tested in guinea pigs (ISO 10993-10) have been met.

Additionally, patient contacting components referenced in this 510(k) are identical to the device components referenced in K193376. These components are I/A HANDPIECE 21G ANGLED 45°, I/A HANDPIECE 21G CURVED, IRR & ASP HANDPIECE BIMANUAL FRONT, IRR & ASP HANDPIECE BIMANUAL, PHACO SET PLUS 21G BICONICAL 15°, PHACO SET PLUS 21G FLARED 30°, PHACO SET PLUS 21G BICONICAL 30°, tips for PHACO SET (flared tip 30°, biconical tip 15°, biconical tip 30°) Sleeve, test chamber set plus 21G, DIATHERMY FORCEPS.

*Sterility Testing*

The sterilization cycle B-01 /B-01x was validated to achieve a sterility assurance level (SAL) of $10^{-6}$ according to ISO 11135:2014. Additionally, visual inspection, micro-biological dusting, seal strength, dye penetration and bubble leak testing was performed to ensure micro-biological barrier function met specifications. Testing passed.

Additionally, after the sterilization process was completed, testing on the patient contacting components for the accessories to measure ethylene oxide (EO) and ethylene chlorohydrin residual (ECH) levels, as well as Limulus Amebocyte Lysate (LAL) levels was conducted. Testing passed.

The following standards were followed: ISO 11135, ISO 14644-1, ISO 14644-2, ASTM F1608, ISO 11607-1, ASTM F1886/F1886M, ASTM F88/F88M and EN 868-5, ASTM F1929, ASTM F2096, AAMI TIR 30, AAMI TIR 12, AAMI TIR 34, AAMI TIR ST81, ISO 15883-1.

*Software Testing*

Subject Device 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.

*Electrical Safety/EMC Testing*

Electrical, Thermal, EMC testing was conducted in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-2 standards. Testing passed.

*Additional Bench Testing*

In addition to testing mentioned above, conformance to IEC 80601-2-58 and IEC 60529 was demonstrated by testing for occlusion break response, fluidics assessments, spring-eye model, and emersion testing was performed. Testing passed.

**Clinical Performance Testing**

Clinical studies were not required since the system does not introduce a new methodology or new/expanded clinical claims.

## 8. CONCLUSION

The indications for use are equivalent 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 reference 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.