June 27, 2024

Oertli Instrumente AG
℅ Meagan Fagan
Principal Consultant, CardioMed Device Consultants LLC
CardioMed Device Consultants LLC
1783 Forest Drive
Suite 254
Annapolis, Maryland 21401

Re: K233398
Trade/Device Name: Faros Surgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, GEI
Dated: May 28, 2024
Received: May 28, 2024

Dear Meagan Fagan:

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233398

Device Name
Faros Surgical System

Indications for Use *(Describe)*
The Faros is a surgery system used by ophthalmologists during cataract surgery. It is designed for use in anterior segment procedures that require simultaneous lens fragmentation, irrigation and aspiration, as well as ancillary functions such as vitreous cutting along with bipolar diathermy.

Faros is used for these surgical interventions in the anterior eye segment:

– Irrigation and aspiration (I/Afunction)
– Ultrasound phaco (PHACO function)
– Biopolar diathermy for hemostasis and coaptation of the conjunctiva (DIA function)
– Bipolar diathermic capsulotomy (CAPS function)
– Operation of a vitrectomy instrument (VIT function)

The device may only be used with the instruments recommended and supplied by Oertli.

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.

510(k) Summary

(as required by 21 CFR 807.92)

Faros Surgical System

510(k) K233398

Date Prepared	June 20th, 2024
Applicant	Oertli Instrumente AG Hafnerwisenstrasse 4 9442 Berneck Switzerland
Contact Name: Title: Email: Telephone:	Ms. Marianne Kesseli Regulatory Affairs Manager marianne.kesseli@oertli-instruments.com +41 71 747 42 74
Name of the Device	Faros Surgical System
Common Name	Phacofragementation Unit
Classification Name	Phacofragmentation System (21 CFR 886.4670)
Regulatory Class	II
Product Code	HQC
Subsequent Product Codes	HQE, GEI
Predicate Device	CataRhex 3 Cataract Surgery System (K133562)

Intended Use/Indications for Use:

The Faros is a surgery system used by ophthalmologists during cataract surgery. It is designed for use in anterior segment procedures that require simultaneous lens fragmentation, irrigation and aspiration, as well as ancillary functions such as vitreous cutting along with bipolar diathermy.

Faros is used for these surgical interventions in the anterior eye segment:

- Irrigation and aspiration (I/A function)
- Ultrasound phaco (PHACO function)
- Bipolar diathermy for hemostasis and coaptation of the conjunctiva (DIA function)
- Bipolar diathermic capsulotomy (CAPS function)
- Operation of a vitrectomy instrument (VIT function)

The device may only be used with the instruments recommended and supplied by Oertli.

Device Description

The Faros Surgery System is designed for use in anterior segment eye surgery, primarily for removal of cataractous lenses. The system generates high-frequency ultrasound to emulsify the eye's natural lens,

which is then aspirated using fluidics. The system also includes functions for bipolar diathermy (for hemostasis, conjunctival coaptation, and capsulotomy), as well as for anterior vitrectomy, a procedure associated with cataract surgery.

The Faros Surgery System consists of a main unit (an AC-powered tower-like device with a control panel governing surgical functions, and ports to connect surgical instruments), with a mounted infusion pole and a foot pedal used by the surgeon to control system functions. An irrigation/aspiration tubing system is mounted onto the main unit. Surgical handpieces connected to the main unit are used to perform irrigation and aspiration, ultrasound phacoemulsification, bipolar diathermy, bipolar diathermic capsulotomy, and anterior vitrectomy functions.

Comparison with Predicate Device

Comparison of the Faros Surgery System and the predicate device shows that the technological characteristics of the subject device (Faros Surgery System) such as the software and operating principle are similar to the currently marketed predicate device. The intended use of the subject device and the predicate are the same.

	Subject Device - Faros	**Predicate Device - CataRhex 3**
Manufacturer	Oertli Instrumente AG	Oertli Instrumente AG
510(k)	K233398	K133562
Indication for Use/Intended Use	The Faros Surgery System is used by ophthalmologists during cataract surgery. It is designed for use in anterior segment procedures that require simultaneous lens fragmentation, irrigation, and aspiration, as well as ancillary functions such as vitreous cutting along with bipolar diathermy. The Faros Surgery System is used for these surgical interventions in the anterior eye segment: • Irrigation and aspiration (I/A function) • Ultrasound phaco (PHACO function) • Biopolar diathermy for hemostasis and coaptation of the conjunctiva (DIA function) • Bipolar diathermic capsulotomy (CAPS function) • Operation of a vitrectomy instrument (VIT function) The device may only be used with instruments recommended and supplied by Oertli Instrumente AG.	The CataRhex 3 is a surgery system used by ophthalmologists during cataract surgery. It is designed for use in anterior segment procedures that require simultaneous lens fragmentation, irrigation and aspiration, as well as ancillary functions such as vitreous cutting along with bipolar diathermy. The CataRhex 3 is used for surgical interventions in the anterior eye segment: • Irrigation and aspiration (I/A function) • Ultrasound phaco (PHACO function) • Biopolar diathermy for hemostasis and coaptation of the conjunctiva (DIA function) • Bipolar diathermic capsulotomy (CAPS function) • Operation of a vitrectomy instrument (VIT function) The device may only be used with instruments recommended and supplied by Oertli Instrumente AG.
Hardware Design	Main unit, tower-like device Transportable: mobile Foot pedal with additional switches Control panel with backlit keys, with additional keys Automated irrigation pole Colour coded ports for hand pieces Voltage indicator LED Fluidic system Optional instrument table	Main unit, compact console Transportable: portable Foot pedal Control panel with backlit keys Manual irrigation pole Colour coded ports for hand pieces Fluidic system
Software	Software features: • continuous state of device monitoring • control signals generation • interfacing the parts of the device	Software features: • continuous state of device monitoring • control signals generation • interfacing the parts of the device
Electrical data	Mains voltage: 100 – 240 VAC Mains frequency: 50 – 60 Hz Power consumption: 150 VA Operating mode: continuous	Mains voltage: 100 – 240 VAC Mains frequency: 50/60 Hz Power consumption: 280 VA Operating mode: continuous
Irrigation / Aspiration	Gravity feed irrigation	Gravity feed irrigation

	Subject Device - Faros	Predicate Device - CataRhex 3
Function	I/A pump principle: peristaltic I/A modes	I/A pump principle: peristaltic I/A modes
Phaco Function	Ultrasonic emulsification Oscillation: longitudinal Operating frequency: 28 kHz Phaco modes Preset aspiration mode called SPEEP	Ultrasonic emulsification Oscillation: longitudinal Operating frequency: 28 kHz Phaco modes Preset aspiration mode called CORTEX
Diathermy Function	Bipolar diathermy Capsulotomy Diathermy modes Operating frequency: 500 kHz	Bipolar diathermy Capsulotomy Diathermy modes Operating frequency: 500 kHz
Vitrectomy Function	Cutting principle: pneumatic Push and pull movement Cutting design: guillotine	Cutting principle: pneumatic Push and pull movement Cutting design: guillotine

Summary of Performance Data

The Faros Surgery System and the predicate device, CataRhex 3, have similar safety, effectiveness, and performance profiles. Technological characteristics affecting surgical performance are similar to those of the predicate CataRhex 3. Non-clinical testing has demonstrated that the Faros Surgery System complies with specifications and requirements established for the Faros Surgery System and the proposed subject device is substantially equivalent to the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

The Faros Surgery System electrical safety and electromagnetic compatibility has been evaluated and found to be in compliance with:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- FDA Guidance Electromagnetic Compatibility (EMC) of Medical Devices, 2022-06

- IEC 60601-1-2 Edition 4.1 2020-09
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 60601-2-2 Edition 6.0 2017-03
  Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

- IEC 80601-2-58 Edition 2.0 2014-09
  Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery [Including AMENDMENT 1 (2016)]

Software

The Faros Surgery System software has been evaluated and found to be in compliance with:

- FDA Guidance, Content of Premarket Submissions for Device Software Functions, 2023-06

- IEC 62304 Edition 1.1 2015-06
  Medical device software - Software life cycle processes

Cybersecurity

The Faros Surgery System cybersecurity has been evaluated and found to be in compliance with:

- FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, 2023-09
- FDA Guidance for Post-market Management of Cybersecurity in Medical Devices, 2016-12-28
- AAMI TIR57:2016
  Principles for medical device security - Risk management
- AAMI TIR97:2019
  Principles for medical device security - Postmarket risk management for device manufacturers
- ANSI AAMI SW96:2023
  Standard for medical device security - Security risk management for device manufacturers
- IEC 81001-5-1 Edition 1.0 2021-12
  Health software and health IT systems safety effectiveness and security - Part 5-1: Security - Activities in the product life cycle
- ISO/IEC 29147:2018-10
  Information technology – Security techniques – Vulnerability disclosure
- ISO/IEC 30111:2019-10
  Information technology – Security techniques – Vulnerability handling processes
- FIRST CVSS v3.X Common Vulnerability Scoring System version 3.X

Usability

The Faros Surgery System usability has been evaluated and found to be in compliance with:

- FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices, 2016-02
- IEC 62366-1 Edition 1.1 2020-06
  Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- IEC 60601-1-6 Edition 3.2 2020-07
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Biocompatibility

The biocompatibility of the Faros Surgery System and its components and accessories was found to be in compliance with:

- FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2023-09
- ISO 10993-1 Fifth edition 2018-08
  Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ISO 10993-5 Third edition 2009-06-01
  Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Processing of Reusable Accessories (Moist Heat)

The reusable accessories of Faros Surgery System were found to be in compliance with:

- ISO 17664-1 Second edition 2021-07
  Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

Sterility of Accessories

The sterile accessories of Faros Surgery System were found to be in compliance with:

- FDA Guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, 2024-01

Conclusion

The Faros surgery system has the same intended use, similar design and functional features as the predicate device. Conclusions drawn from the non-clinical tests demonstrate that the Faros Surgery System is substantially equivalent to the predicate device.