September 25, 2019

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Linda van Leeuwen
Regulatory Affairs Officer
Scheijdelveweg 2
3214 VN Zuidland

Re: K190875
Trade/Device Name: EVA Ophthalmic Surgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: August 19, 2019
Received: August 22, 2019

Dear Linda van Leeuwen:

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,

Tieuvi Nguyen, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190875

Device Name
EVA Ophthalmic Surgical system

Indications for Use *(Describe)*
The EVA Ophthalmic surgical system is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e. vitreoretinal) ophthalmic surgery.

In addition, the optional laser is indicated for the following:

Condition:	Treatment:
Diabetic Retinopathy	
* Proliferative Diabetic Retinopathy	Panretinal Photocoagulation
* Clinically Significant Macular Edema	Focal or Grid Laser
Retinal Tear and Detachments	Laser Retinopathy
Lattics Degeneration	Retinal Photocoagulation
Sub-retinal (choroidal) Neovascularization	Focal laser
Retinal Vascular Occlusion	
* Neovascularization secondary to Branch or Central retinal vein occlusion	Scatter Laser Photocoagulation
* Chronic macular edema secondary to Branch or Central retinal vein occlusion	Focal or Grid Laser
Glaucoma	
* Primary Open-angle	Trabeculoplasty
* Closed Angle	Iridotomy or Iridoplasty

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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"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."

5. 510(K) SUMMARY

This summary is in accordance with 21 CFR 807.92.

5.1 Submitter

The submitter of the 510(k) is:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Contact person:

Linda Van Leeuwen, Regulatory Affairs Officer
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Mail: l.vanleeuwen@dorc.eu

Date Prepared: September 20, 2019

5.2 Device

Device Subject to this 510(k):

Trade Name:	EVA Ophthalmic Surgical System
Common Name:	Phacoemulsification/Vitrectomy System
Classification Name:	Class II

The following regulations are applicable for this 510(k):

- 21 CFR 886.4670 Phacofragmentation System (Product Code: HQC)
- 21 CFR 886.4150 Vitreous Aspirating and Cutting Device (Product Code: HQE)
- 21 CFR 886.4390 Ophthalmic Laser (Product Code: HQF)

The purpose of this 510(k) is to obtain clearance for minor improvements to the cleared device. These changes include:

- **Footswitch:** The footswitch of the EVA has been modified to improve ergonomics and simultaneously integrate the laser pedal functionality. An optional separate laser footswitch will remain available if surgeons prefer.

- **Illumination:** Due to quality improvements in the LED output, the light output has been increased to improve illumination with small gauge fibers. However, the system controls the absolute output of the module to 40 lumens as previously cleared. As an example, the illumination output for a 27 gauge fiber has been improved from 5 lumens as cleared to 7 lumens in the proposed system. However, the maximum

output, and maximum exposure to patient, remains at 40 lumens for any fiber as previously cleared. Thus there are no risks introduced with this change.

- **The Posterior Module (Air Functionality):** To support use of EVA for fluid/air exchanges (F-AX), independent of the compressed air / gas supply available, the hardware design of the Posterior (VFIE, Air, Proportional Scissors) module has been modified to provide air through two independent circuits, instead of one as previously cleared. As a result, the air for F-AX is provided by a separate circuit that draws air from the environment (with appropriate filtration), whilst the compressed gas drive for other EVA functions is provided from the pneumatic input (supplied by the surgical setting – typically compressed air or Nitrogen) as per the current design. With this improved design, the compressed gas input of the system will only be used for internal system operation while air needed for surgical use will be derived from filtered, ambient air. Thus, the consumption of compressed gas used to operate the EVA is reduced.

- **Software:** To support these changes the EVA software was upgraded as well as anomaly/bug fixes. A complete detail of these minor improvements can be found in the Software portion of this 510(k) (Section 16 and Annex 5).

- **Sterilization of Reusable Accessories:** Minor changes to the conditions recommended in the labeling have been made and are supported by validation and performance testing included in this 510(k).

- **Shelf life of Disposable Accessories:** The shelf-life of peel pouch packed disposable accessories has been extended to 5-years and is supported by validation and performance testing included in this 510(k).

- **Accessory Changes**: Some packs (combinations of accessories) were discontinued and new configurations added. No new accessories that were not previously cleared were added.

5.3. Predicate Device(s)

Primary Predicate:

510(k) Number	Device
K142877	EVA Ophthalmic Surgical System (DORC)

Additional Predicates:

K101285	Constellation Vision System (Alcon)
K133486	Stellaris PC Vision Enhancement System (Bausch & Lomb)

5.4. Device Description

The EVA Ophthalmic Surgical System (EVA) is a combined anterior and posterior procedure ophthalmic system that was cleared by FDA in March, 2015 (K142877). The EVA is designed for use in anterior and posterior procedures that require infusion, vitreous cutting, aspiration, illumination, irrigation, lens emulsification and fragmentation, cautery, diathermy as well as photocoagulation.

5.5. Indications for Use

The EVA Ophthalmic Surgical System is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

In addition, the optional laser is indicated for the following:

Condition	Treatment
Diabetic Retinopathy	
• Proliferative Diabetic Retinopathy	Panretinal Photocoagulation
• Clinically Significant Macular Edema	Focal or Grid Laser
Retinal Tear and Detachments	Laser Retinopathy
Lattice Degeneration	Retinal Photocoagulation
Sub-retinal (choroidal) Neovascularization	Focal Laser
Retinal Vascular Occlusion	
• Neovascularization secondary to Brand or Central retinal vein occlusion	Scatter Laser Photocoagulation
• Chronic macular edema secondary to Branch or Central retinal vein occlusion	Focal or Grid Laser
Glaucoma	
• Primary Open-angle	Trabeculoplasty
• Closed Angle	Iridotomy or Iridoplasty

5.6. Comparison of Technological Characteristics with the Predicate Devices

There are no indications for use, features or technological of the EVA Ophthalmic Surgical System that have not been previously cleared in the predicate devices.

5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation of the EVA Ophthalmic Surgical System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The EVA Ophthalmic Surgical System 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 health concerns.

All accessories used with the EVA Ophthalmic Surgical System that potentially come into contact with the patient or patient fluid path have been previously cleared.

Biocompatibility testing of accessories has been conducted and confirmed acceptable by cytotoxicity, kligman maximization and intracutaneous irritation testing, in compliance with ISO 10993-1, 10993-5, 10993-10 and 10993-12.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the EVA Ophthalmic Surgical System. The system complies with the IEC 60601-1, EN 60601-2-2 and EN 80601-2-58 standards for safety and EN 60601-1-2 and 47 CFR Part 15 Subpart B for EMC.

Software Verification and Validation Testing

Software verification and validation testing were 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." The software for this

device was 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.

Performance Testing

Although animal and clinical performance testing were not required for the EVA to demonstrate efficacy, safety and substantial equivalence to predicate devices, a variety of laboratory (bench) performance tests have been conducted including:

- Testing to ensure compliance to ISO 15004-2: 2007 "Illuminator Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection"
- Testing to confirm that the light probe tips will not melt at the maximum output of the LED illumination module
- Testing to provide objective evidence that the pneumatic system of the Eva system is compatible with the use of compressed nitrogen (N2) gas or compressed air
- 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"

5.8 Conclusion

As described in this 510(k) Summary, all testing deemed necessary was conducted on the EVA Ophthalmic Surgical System to ensure that the device is substantially equivalent to the predicate device for its intended use when used in accordance with its Instructions for Use.