DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 13, 2015

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Ms. Daniëlle Sleegers MSc.
QA/RA Manager
Scheijdelveweg 2,
3214 VN Zuidland, Netherlands

Re: K142877
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: February 6, 2015
Received: February 9, 2015

Dear Ms. Sleegers:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142877

Device Name: EVA Ophthalmic Surgical System

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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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: Mrs. D.F.J. Sleegers, QA/RA Manager
Phone: +31 181 458080
Email: d.sleegers@dorc.eu

Date Prepared: January 15, 2015

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
- 21 CFR 886.4150 Vitreous Aspirating and Cutting Device
- 21 CFR 886.4390 Ophthalmic Laser

5.3. Predicate Devices

510(k) Number	Device
K081877	Associate 2500 dual and compact systems (DORC)
K101285	Constellation Vision System (Alcon)
K101325	Stellaris PC Vision Enhancement System (Bausch & Lomb)
K102222	Ultimate Vit Enhancer (MID Labs)
K121675	VersaVit (Synergetics)
K062624	Next Generation Laser (PurePoint; Alcon)

5.4. Device Description

The EVA Ophthalmic Surgical System (EVA) is a combined anterior and posterior procedure ophthalmic system that is modular in design and serves as an enhanced version of the currently cleared Associate (K081877). 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

As described in Section 12 of this 510(k) there are no technological characteristics (including operating specifications) or features of the EVA Ophthalmic Surgical System that have not been previously cleared in 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.

With the exception of the cartridges and vitrectomy handpieces 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.

The biocompatibility of the cartridges and vitrectomy handpieces has been evaluated 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 was 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 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"
- 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 vitrectomy cutters will not fail at the normal working pressure (41PSI).
- Testing to determine the durability of the EVA Pump module
- Testing to confirm that the light probe tips will not melt at the maximum output of the LED illumination module.
- Testing to confirm that the waste bags will not rupture when full.
- Testing to confirm that the vitrectomy cutters will not generate particulate matter at the highest cut speed.
- Testing to confirm that reusable accessories can withstand repeat sterilization without impact to device characteristics

Standard #	*Title*
ISO 10993-1: 2009	Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing
ISO 10993-5: 2009	Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-7: 2008	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
ISO 10993-10: 2010	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Sensitization
ISO 10993-12: 2012	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation and Reference Materials
ISO 11135:2007	Sterilization Of Health-Care Products - Ethylene Oxide – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
ISO 14971:2007	Medical Devices: Application Of Risk Management To Medical Devices
ISO 11607-1:2006	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
ISO 11607-2:2007	Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes
ISO 15004-2:2007	Ophthalmic Instruments - Fundamental Requirements And Test Methods - Part 2: Light Hazard Protection
ISO 14644-2:2000	Cleanrooms And Associated Controlled Environments - Part 2: Specifications For Testing And Monitoring To Prove Continued Compliance With ISO 14644-1
ISO 15223-1:2012	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling And Information To Be Supplied - Part 1: General Requirements
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	Medical Electrical Equipment, Part 1 – General Requirements For Safety
EN 60601-1-2 :2007	Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
EN 60601-2-2: 2009: +A11: 2011	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. Clause 202.
EN 80601-2-58: 2008	Medical Electrical Equipment – Part 2-58: Particular Requirements For The Basic Safety And Essential Performance Of Lens Removal Devices And Vitrectomy Devices For Ophthalmic Surgery
EN 60601-1-6:2007/ AC: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60825-1 Edition 2.0 2007-03	Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
EN 60601-2-22:1996	Medical Electrical Equipment. Particular Requirements For Safety Specification For Diagnostic And Therapeutic Laser Equipment
EN ISO 17664:2004	Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices

Standard #	*Title*
EN 1707:1996	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment
ISO 594-1:1986	Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment- Part 1: General Requirements
ISO 9626:1991	Stainless Steel Needle Tubing For Manufacture Of Medical Devices
ISO 13402:1995	Surgical And Dental Hand Instruments - Determination Of Resistance Against Autoclaving, Corrosion And Thermal Exposure
ISO 15883-2:2009	Washer-Disinfectors - Part 2: Requirements And Tests For Washer Disinfectors Employing Thermal Disinfection For Surgical Instruments, Anaesthetic Equipment, Bowls, Dishes, Receivers, Utensils, Glassware, Etc. (ISO 15883-2:2006,IDT)
EN ISO 10524-4: 2008	Pressure Regulators For Use With Medical Gases- Part 4: Low- Pressure Regulators Intended For Incorporation Into Medical Equipment
EN ISO 10079-3: 2009	Medical Suction Equipment - Part 3: Suction Equipment Powered From A Vacuum Or Pressure Source
EN ISO 5359:2008	Low-Pressure Hose Assemblies For Use With Medical Gases
IEC 61847:1998	Ultrasonics Surgical Systems Measurement And Declaration Of The Basic Output Characteristics
EN 62366:2008	Medical Devices - Application Of Usability Engineering To Medical Devices
EN 556-1: 2001/ C1	Sterilization Of Medical Devices- Requirements For Medical Devices To Be Designated 'Sterile'- Part 1: Requirements For Terminally Sterilized Medical Devices
ISO 11137-1: 2006/ C1	Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11137-2: 2012	Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose
EN ISO 11140-1: 2009	Sterilization Of Health Care Products - Chemical Indicators - Part 1: General Requirements
EN ISO 11737-1: 2006/ AC: 2009	Sterilization Of Medical Devices - Microbiological Methods - Part 1: Determination Of A Population Of Microorganisms On Products
ISO 17665-1:2006	Sterilization Of Health Care Products - Moist Heat - Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ANSI Z136.1:2007	American National Standard for Safe Use of Lasers
EN 62304:2006	Medical device software – Software life-cycle processes

5.8 Conclusion

The performance data described herein support the safety of the device and the hardware and software verification and validation demonstrate that the EVA Ophthalmic Surgical System is substantially equivalent to the predicate devices and should perform as intended in the specified use conditions.