March 26, 2019

Alcon Laboratories, Inc.
Ms. Ophelia Biggs
Director, Global Regulatory Affairs Projects, Surgical Instrumentation
20511 Lake Forest Drive
Lake Forest, CA 92630

Re: K190392
Trade/Device Name: WaveLight FS200 Patient Interface 1515
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, HNO
Dated: February 28, 2019
Received: March 1, 2019

Dear Ms. Biggs:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Alexander Beylin -S 2019.03.26 16:54:33 -04'00'

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

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)*
K190392

Device Name
WaveLight FS200 Patient Interface 1515

Indications for Use *(Describe)*
The WaveLight FS200 Patient Interface 1515 is indicated to be used only with the WaveLight FS200 Laser System, consistent with the cleared Indications for Use for this ophthalmic surgical laser.

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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K190392 510(k) Summary

This summary document is prepared in accordance with Section 21 CFR 807.92(c).

Administrative Information

510(k) Submitter:

Alcon Research, Ltd. (on behalf of Alcon Laboratories, Inc.)
20511 Lake Forest Drive
Lake Forest, CA 92630 USA

Contact Person:

Ophelia Biggs
Director, Global Regulatory Affairs Projects, Surgical Instrumentation
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Lake Forest, CA 92630
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Email: ophelia.biggs@alcon.com

Date Prepared: November 1, 2018

Subject Device of this Special 510(k):

Trade/Proprietary Name:	WaveLight® FS200 Patient Interface 1515
Submitter:	Alcon Research, Ltd. 20511 Lake Forest Drive Lake Forest, CA 92630 USA
Common Name:	Sterile Consumable (disposable)
Classification Name:	Consumable for use with a powered laser surgical instrument (21 CFR 878.4810)
Device Classification:	II
FDA Panel:	General and Plastic Surgery / Ophthalmic
Product Code:	GEX/HNO

Predicate Device:

Trade/Proprietary Name:	WaveLight® FS200 Patient Interface 1505
510(k) Number:	K121031
FDA Clearance Date:	June 21, 2012
Submitter:	Alcon Research, Ltd. 6201 South Freeway Fort Worth, TX 76134-2099 USA
Common Name:	Sterile Consumable (disposable)

Classification Name:	Consumable for use with a powered laser surgical instrument (21 CFR 878.4810)
Device Classification:	II
FDA Panel:	General and Plastic Surgery / Ophthalmic
Product Code:	GEX/HNO

Device Description

The WaveLight® FS200 Patient Interface 1515 is a patient contact consumable (disposable) consisting of a tubing system with an integrated suction ring and an applanation cone. The flat bottom of the cone is used as an applanation plate for the patient's cornea.

Indications for Use

The WaveLight® FS200 Patient Interface 1515 is indicated to be used only with the WaveLight® FS200 Laser System, consistent with the cleared Indications for Use for this ophthalmic surgical laser.

Statement of How the Technological Characteristics of the Device Compare to Those of the Predicate Device

The technological characteristics of the WaveLight® FS200 Patient Interface 1515 are equivalent to those of the predicate device. The WaveLight® FS200 Patient Interface 1515 and its predicate device, the WaveLight® FS200 Patient Interface 1505, are alternative consumables for use with the WaveLight® FS200 Laser System. They both consist of a tubing system with integrated suction ring and an applanation cone.

The operating principles and mechanism of action are the same between subject and predicate devices. The dimensions are also the same. The main differences are in the primary packaging configuration, and in the type of material used for the tubing system and filter housing.

The predicate device is packaged using a double-blister packaging configuration, while the WaveLight® FS200 Patient Interface 1515 uses a single-blister packaging design. Compared to the predicate device, the WaveLight® FS200 Patient Interface 1515 now incorporates DEHP-free materials in its tubing system and filter housing.

Brief Summary of Non-Clinical Tests and Results

Biocompatibility

Biocompatibility evaluations of materials coming into contact with the patient or fluid path have been successfully performed against the applicable ISO 10993 standards, taking into account the FDA-recognized consensus standard ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (Recognition number 2-220). The materials in the subject device do not introduce chemicals that raise biocompatibility concerns.

Sterility

The WaveLight® FS200 Patient Interface 1515 is provided sterile and is intended for single use only. The product is sterilized using ethylene oxide (EtO). The EtO sterilization cycle has been validated according to the FDA-recognized consensus standard ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices* (Recognition number 14-452). The sterilization process for the WaveLight® FS200 Patient Interface 1515 has been validated to achieve a sterility assurance level (SAL) of 10^{-6}.

Packaging and Shelf Life

Packaging and shelf life was successfully validated according to the FDA-recognized consensus standards ISO 11607-1:2017 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging systems [Including amendment 1 (2014)]* and ASTM F1980-16 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* (Recognition Number 14-497). The sterile barrier system is maintained during sterilization, distribution, and a shelf life of up to 3 years.

Transport Stability

Transport stability was successfully validated according to the FDA-recognized consensus standard ISO 11607-1:2017 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials sterile barrier systems and packaging systems [Including amendment 1 (2014)]*. The sterile barrier system is maintained after subjecting the subject device to extreme transport challenge scenarios.

Functional Testing

Functional tests were performed after sterilization, transportation, and aging (accelerated and real-time). Tests demonstrated that the performance of the WaveLight® FS200 Patient Interface 1515 is equivalent to that of the predicate device, the WaveLight® FS200 Patient Interface 1505.

Conclusion

Non-clinical testing successfully demonstrated that the technological characteristics of the WaveLight® FS200 Patient Interface 1515 are substantially equivalent to those of the predicate device.