DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 16, 2014

Sensor Medical Technology, LLC
c/o Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K142715
Trade/Device Name: Sensor Medical Family of Vitrectomy Lenses and Products
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) Diagnostic Contact Lens
Regulatory Class: Class II
Product Code: HJK, HNR
Dated: October 20, 2014
Received: October 21, 2014

Dear Ms. O'Connell:

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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142715

Device Name
Sensor Medical Family of Vitrectomy Lenses and Products

Indications for Use *(Describe)*
The Sensor Medical Family of Vitrectomy Lenses and Products allows visualization of the ocular fundus, vitreous and retinal structures during vitrectomy surgery.

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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510(k) SUMMARY

Sensor Medical Technology LLC
Sensor Medical Family of Vitrectomy Lenses and Products

Name of Device and Name/Address of Sponsor
Sensor Medical Family of Vitrectomy Lenses and Products

Sensor Medical Technology LLC
23175 224th Place SE, Suite C
Maple Valley, WA 98038

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
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Date Prepared: December 11, 2014

Common or Usual Name
PMMA diagnostic contact lens and ophthalmic forceps

Classification Name and Regulation
Polymethylmethacrylate (PMMA) diagnostic contact lens
21 CFR 886.1385, HJK
Ophthalmic Panel

Manual ophthalmic surgical instrument
21 CRF 886.4350, HNR
Ophthalmic Panel

Predicate Devices
Ocular Instruments Disposable Vitrectomy Lens Kit (K012096)

Intended Use / Indications for Use
The Sensor Medical Family of Vitrectomy Lenses and Products allows visualization of the ocular fundus, vitreous and retinal structures during vitrectomy surgery.

Device Description
The Sensor Medical Family of Vitrectomy Lenses and Products includes single-use, disposable, sterile devices for use during vitrectomy surgery. The following devices are included in the family: Plano Lens, Magnifier Lens, Bi-Concave Lens, 20 degree Prism Lens, 30 degree Prism Lens, Osher 78 D Lens, Suture Ring, Silicone Ring, and Lens Forceps.

The Sensor Medical Family of Vitrectomy Lenses and Products is designed around the classic Goldmann contact lens. Each style of lens is of similar design, with slight variations in the posterior surface shape to provide excellent visualization of the ocular anatomical areas for the particular intended use. When used in conjunction with an operating microscope, the ophthalmic lenses provide a binocular and stereoscopic view of the specific optical region of the eye.

The lenses typically consist of a PMMA (acrylic) optical element that is applied for a short period of time directly on the globe or cornea of the eye.

Performance Data
No performance data is provided since no new questions of safety and effectiveness are raised.

Substantial Equivalence
The Sensor Medical Family of Vitrectomy Lenses and Products is substantially equivalent to the Ocular Instruments Disposable Vitrectomy Lens Kit (K012096) (the "predicate device") that the FDA has already cleared. The Sensor Medical Family of Vitrectomy Lenses and Products has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate.

Each of the Sensor Medical Family of Vitrectomy Lenses is equivalent to one of the lenses from the predicate device family of lenses. Each individual lens is compared with the relevant lens from the predicate family. Each individual lens had identical specifications to its identified predicate with the exception of the following:

The Sensor Magnifier Lens is equivalent to the Ocular Instruments Magnifying Lens. Both are used for manipulation of retinal membranes and both have a 30 degree field of view. The magnification differs slightly; 1.2x for the Sensor lens and 1.49x for the Ocular Instruments lens. This is a very marginal difference in that the dilation of the patient's pupil is the limiting factor during a vitrectomy. Therefore, this minor difference has not impact on the safety or effectiveness of the Sensor Magnifier Lens.

The Sensor 20 degree Prism Lens is equivalent to the Ocular Instruments 20 degree Disposable Vitrectomy Lens. Both lenses are used for visualization of peripheral posterior structures and both have a 1.02x magnification. The field of view is 36 degrees for the Sensor lens and 33 degrees for the Ocular Instruments lens. This very minor difference has no impact on the safety or effectiveness of the lens during vitrectomy surgery as the patient's pupil dilation is the limiting factor.

The Sensor 30 degree Prism Lens is equivalent to the Ocular Instruments 30 degree Disposable Vitrectomy Lens. Both lenses are used for visualization of peripheral posterior structures and both have a 1.02x magnification. The field of view is 36 degrees for the Sensor lens and 33 degrees for the Ocular Instruments lens. This very minor difference has no impact on the safety or effectiveness of the lens during vitrectomy surgery as the patient's pupil dilation is the limiting factor.

The Sensor Osher 78 degree Lens is equivalent to the Ocular Instruments 78 degree Maxfield Lens. Both lenses are used for visualization of peripheral posterior structures and both have a 0.77x magnification. The field of view is 80 degrees for the Sensor lens and 85 degrees for the Ocular Instruments lens. This very minor difference has no impact on the safety or effectiveness of the lens during vitrectomy surgery as the patient's pupil dilation is the limiting factor.

There are some very minor variations in specifications in comparing some of the lenses that do not affect the safety or efficacy of the lenses. However the variations are so slight that the lenses are interchangeable with the various manufacturers suture rings, lens forceps or silicone rings.

Minor differences between the subject device and the predicate device do not raise new questions of safety or efficacy. The Sensor Medical Family of Vitrectomy Lenses and Products is as safe and effective as its predicate device, and thus, substantially equivalent.