



Food and Drug Administration
10903 New Hampshire Avenue
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October 13, 2015

Sensor Medical Technology, LLC
% Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K152308

Trade/Device Name: Sensor Medical Single Use Tonometer Prism
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: August 13, 2015
Received: August 17, 2015

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,


Deborah L. Falls -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

Indications for Use

510(k) Number (if known)

Device Name

Sensor Medical Single Use Tonometer Prism

Indications for Use (Describe)

The Sensor Medical Single Use Tonometer Prism is intended for use as a disposable applanating and optical doubling prism for Goldmann style applanation tonometers.

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.

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510(k) SUMMARY

Sensor Medical Technology LLC Sensor Medical Single Use Tonometer Prism

Name of Device and Name/Address of Sponsor

Sensor Medical Single Use Tonometer Prism

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

Date Prepared: July 24, 2015

Common or Usual Name

Tonometer Prism

Classification Name and Regulation

Manual Tonometer
21 CFR 886.1930, HKY
Ophthalmic Panel

Predicate Devices

Luneau Tonometer Separation Prisms (K023838)

Intended Use / Indications for Use

The Sensor Medical Single Use Tonometer Prism is intended for use as a disposable applanating and optical doubling prism for Goldmann style applanation tonometer.

Device Description

The Sensor Medical Single Use Tonometer Prism is used as the optical image doubling prism for Goldmann applanation style tonometers.

The prism is a precise optical replacement for the current glass Goldmann

tonometer.

The Sensor Medical Single Use Tonometer Prism is made from PMMA. The corneal contact diameter is 6.6 +/-0.1mm. The total length of the prism is 30.0 +/- 0.1mm. The prism weighs 1.8 +/- 0.1 g.

Performance Data

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

Substantial Equivalence

Sensor Medical Technology, LLC believes that the Sensor Medical Single Use Tonometer Prism described in this notification and for use under the conditions of proposed labeling is a Class II device which is substantially equivalent to a legally marketed predicate device.

The Sensor Medical Single Use Tonometer Prism is substantially equivalent to the Luneau Tonometer Separation Prisms (K023838) (the “predicate device”) that the FDA has already cleared. The Sensor Medical Single Use Tonometer Prism has the same intended use, technological characteristics, and principles of operation as the previously cleared predicate.

The intended use of the Sensor Medical Single Use Tonometer Prism and the intended use of the Luneau Tonometer Separation Prisms cleared in K023838 are identical. Both devices are disposable, sterile applanating tonometer prisms used in Goldmann style tonometers for measurement of intraocular pressure. Both devices are prescription devices used by trained professionals.

The Sensor Medical Single Use Tonometer Prism has the same technological characteristics as the Luneau Tonometer Separation Prisms cleared in K023838. Both devices are disposable applanating and optical doubling prisms for use in Goldmann style applanation tonometers for measurement of intraocular pressure. Both devices are provided sterile for single use. Both devices are made from PMMA and both devices have the same size and weight.

In summary, Sensor Medical Single Use Tonometer Prism has the same intended use as the previously cleared predicate device. In addition, the Sensor Medical Single Use Tonometer Prism has the same technological characteristics as its predicate. Therefore, the Sensor Medical Single Use Tonometer Prism is substantially equivalent to the predicate device.