DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 31, 2015

Keeler Instruments, Inc.
Mr. Eugene R. Van Arsdale
Marketing Manager
456 Parkway
Broomall, PA 19008

Re: K152644
Trade/Device Name: Keeler Disposable Tonomate, Keeler Disposable Tonomate
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II,
Product Code: HKY
Dated: October 16, 2015
Received: October 19, 2015

Dear Mr. Van Arsdale,

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,

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

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)*
K152644

Device Name
Keeler Applanation Tonometer
Digital Keeler Applanation Tonometer

Indications for Use *(Describe)*
The Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer are indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.

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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Keeler
Ophthalmic Instruments

510(k) Summary of Safety and Effectiveness

1.1 Submitter's Information

The submitter of this special pre-market notification is:

Name:	Dr. Irina Proutski (Head of Regulatory and Quality Affairs).
Address:	Keeler Limited, Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK
Company Phone No:	+44 (0) 1753 827125
Company Fax No:	+44 (0) 1753 827145
Contact Person:	Dr Irina Proutski
Date summary prepared:	15th July 2015

1.2 Device Identification (Unmodified)

Device Trade Name:	Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer
Common Name:	Tonometer, manual
Class:	II
Classification Panel:	86
Product Code:	HKY
Regulation Number:	886.1930

1.3 Device Description

1.3.1 Unmodified Device

The unmodified device is Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer. Both are Goldman type tonometers to measure intraocular pressure to aid in the screening and diagnosis of glaucoma.
In applanation tonometry the intraocular pressure (IOP) is calculated from the force required to flatten a constant area of the cornea. Goldmann tonometry is considered to be the gold standard test and is the most widely accepted method in current practice.

1.3.2 Modified Device

The Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer with non-disposable (re-usable) applanation prism were cleared for US marketing in 2009, 2013 and 2014 under previous pre-market notifications.
The intended use and functionality of the Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer are unchanged by use of this disposable accessory (Keeler Tonomate).
The Keeler Tonomate is an OBL product manufactured and privately labelled under subcontract to Keeler by Phakos (62, Rue Kleber, Montreuil 93100, France) before shipment to Keeler for distribution.
The Keeler Tonomate is pre-sterilized with ethylene dioxide by Phakos sub-contractor, SteriServices (20 Rue Des Canadiens, Bernay 27300, France). Phakos is registered with FDA for supply of sterile contact lenses and OBL-manufacturing of Keeler Disposable Cryo Probes (Establishment Registration No. 3006142778) which are sterilized by the same sub-contractor.
The Keeler Tonomate is a flattening cone containing biprism that converts the circular image of the flattened cornea to two semicircles that touch and cross at the time of flattening the cornea. The force required to flatten the cornea is converted to millimeters of mercury (mmHg).

1.4 Indications for Use

The following indications for use for the Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer remain unchanged by introduction of the Keeler Tonomate:

“The Keeler Applanation Tonometer and the Digital Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.“

1.5 Comparison with Cleared Device

The device modification submission has been prepared to obtain clearance to market a disposable version of the applanation prism used as an accessory with Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer.
The Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer with the Keeler Tonomate (disposable version of the Applanation Prism) are considered to be substantially equivalent to the Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer with non-disposable (re-usable) Applanation Prism in the following original submissions:

Keeler Applanation Tonometer T-Type KAT; R-Type KAT (K093445)
Digital Keeler Applanation Tonometer D-KAT T-Type, D-KAT R-Type (K133234)

1.6 Summary of Design Control Activities

In accordance with FDA guidance on submission of a Special 510(k), risk management, verification/validation and other related activities were carried out to assure continuing safety and effectiveness of the device.
The original version of the Phakos Tonoclean tonometer prism was developed under their own design control system which ensured the required activities were carried out, including packaging and sterilization cycle validation.
No clinical investigations were required as the safety and effectiveness in clinical use of the tonometer prism has been well established for the original equipment manufacturer (OEM) version of the prism, which has been sold into the European market by the manufacturer since 2014. In addition, the technical characteristics of Phakos Tonoclean and Keeler Tonomate were kept identical to those of the non-disposable prisms which were in successful use since 1950s.

1.7 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Keeler Limited conclude that the addition of the Keeler Tonomate (a disposable version of the Applanation prism) does not raise new issues on the safety and effectiveness of the Keeler Applanation Tonometer and Digital Keeler Applanation Tonometer.