K093445

Abbreviated 510(k) Summary

Manufacturer's information

Company Name: Keeler Ltd

JAN 19 2010

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Submitter's information

The submitter of this pre-market notification is:

Mr. Eugene VanArsdale (Marketing Manager).
Keeler Instruments Inc
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Date summary prepared: January 04, 2010

Proposed Device Identification

Device Trade Name:	Keeler Applanation Tonometer
Common Name:	Goldmann Tonometer
Class:	2
Classification Panel:	86
Product Code:	HKY
Regulation Number:	886.1930

Indications for Use

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

Device Description and intended use

The Keeler Applanation Tonometer is a screening device used to measure intraocular pressure which is one of the factors considered in diagnosing glaucoma. The product is a non-active medical device and is completely mechanical, therefore without electrical components.

The operation principal is based on Goldmann applanation method.
The product is installed on a special support on the slit lamp and is used in conjunction with commercially available slit lamps.

Predicated Devices
Keeler Applanation Tonometer is judged to be substantially equivalent in safety, effectiveness and intended use to the following legally marketed devices:

Substantial Equivalence 1:
Predicate Device: F900 and A900, CSO
510(k) No: K022054
Manufacturer: CSO S.R.L

Substantial Equivalence 2:
Predicate Device: Haag Streit AT 900
510(k) No: K981432
Manufacturer: Haag-Streit

Substantial Equivalence Comparison
Table below shows the comparison of Keeler Applanation Tonometer to predicate devices. The comparison of intended use and technological features of KAT indicate that the device is substantially equivalent to legally marketed predicate devices.

Comparison of Goldmann Tonometer Technological Characteristics Keeler Applanation Tonometer vs. CSO Tonometer			
Criteria	**Predicate Device F900 and A900, CSO Tonometers (Re:510(k) K022054)**		**Keeler Applanation Tonometer (KAT)**
Type	Manual contact Tonometer		Manual contact Tonometer
Indication	Intraocular Pressure (IOP) measurement		Intraocular Pressure (IOP) measurement
Design	Slit lamp mounted manual dial		Slit lamp mounted manual dial
Prism Material	Acrylic (PMMA)		Acrylic (PMMA)
Measurement Range	0-80mmHg		0-80mmHg
Measurement technique	Applanation		Applanation
Measurement Method	Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gmf (1.96mN))		Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gmf (1.96mN))
Calibration	Maintenance and		Maintenance and calibration required

	calibration required		
Intended use	Instrument is intended to measure pressure by applanation (applying a small flat disc to cornea)		Instrument is intended to measure pressure by applanation (applying a small flat disc to cornea)

Comparison of Goldmann Tonometer Technological Characteristics Keeler Applanation Tonometer vs. Haag-Streit AT 900			
Criteria	**Predicate Device Haag-Streit AT 900 (Re:510(k) K0981432)**		**Keeler Applanation Tonometer (KAT)**
Type	Manual contact Tonometer		Manual contact Tonometer
Indication	Intraocular Pressure (IOP) measurement		Intraocular Pressure (IOP) measurement
Design	Slit lamp mounted manual dial		Slit lamp mounted manual dial
Measurement Range	0-80mmHg		0-80mmHg
Measurement technique	Applanation		Applanation
Measurement Method	Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gmf (1.96mN))		Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gmf (1.96mN))
Calibration	Maintenance and Calibration required		Maintenance and calibration required
Intended use	Instrument is intended to measure pressure by applanation (applying a small flat disc to cornea)		Instrument is intended to measure pressure by applanation (applying a small flat disc to cornea)

Note: There is no difference between Predicate devices and Keeler Applanation Tonometer.

Summary of Performance Testing

The performance of Keeler Applanation Tonometer has been evaluated in bench testing, comparative study with its predicative devices and field trial.

Bench testing was carried out using arrangement as per Tonometer Standard BSENISO 8612: 2001. Keeler Applanation Tonometer units under test are verified against the nominal requirements of Tonometer standard.

Bench testing arrangement was also used to carry out comparative study, i.e. comparing Keeler Applanation Tonometer with its predicate devices. Keeler Applanation Tonometer and its predicate devices were subject to the same nominal requirements as set by the Tonometer standard and the results demonstrate that they are substantially equivalent.

Field test was conducted by ophthalmic professional to compare Keeler Applanation Tonometer with its predicate device and the findings are comparable.

Based on the results of the performance testing, the Keeler Applanation Tonometer is judged to be as safe, as effective and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Keeler Instruments, Inc.
c/o Mr. Eugene R. VanArsdale
Marketing Director
456 Parkway
Broomall, PA 19008

JAN 19 2010

Re: K093445
Trade/Device Name: Keeler Applanation Tonometer; T-Type KAT, K-Type KAT, (KAT)
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: II
Product Code: HKY
Dated: October 19, 2009
Received: October 21, 2009

Dear Mr. VanArsdale:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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: Keeler Applanation Tonometer (KAT)

Indications for Use:

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

Prescription Use __√_____ (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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093445