

510(k) Summary of Safety and Effectiveness

1. Submitter Name and Address

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Date Prepared: 20 February 2014

2. Device Name (Unmodified)

Trade Name:	Keeler Applanation Tonometer (KAT)
Common/Usual Name:	T-Type KAT, R-Type KAT
Classification Name:	Tonometer and Accessories
Regulation No:	886.1930
Device Regulatory Class:	II
Review Panel:	Ophthalmic
Product Code:	HKY
Premarket Notification (510(k)) Number:	K093445

3. Proposed Modification

The proposed modification described in this Traditional 510(k) covers the introduction of a digital variant to the current Keeler Applanation Tonometer (KAT) range. This modification is intended to provide an addition to the Keeler Applanation Tonometers product range.

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.

The new digital variant of the KAT uses the same operating principle found in all Goldmann type tonometers.

The internal mechanism of the KAT has been modified to permit the measured IOP to be read on an LED display. The LED display allows for easy reading by the user rather than reading from the dial as is currently the case with standard Goldmann tonometers.

The intended use of the Digital Keeler Applanation Tonometer (D-KAT) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

4. Device Description

The Digital 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 an active medical device, powered by a single AA battery. The operation principal is based on Goldmann applanation method.

The Indications for Use, Operating principles, measurement accuracy and repeatability are the same as the predicate device. The device is used in conjunction with commercially available Slit lamps and can be used with the same mounting options as predicate device.

The D-KAT uses the same Applanation Prisms as the predicate Keeler Applanation Tonometer.

Method of Operation

In applanation tonometry the intraocular pressure 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.

The Digital Keeler Applanation Tonometer functions in accordance with the 'Goldmann method' i.e. the measuring of pressure to maintain a uniform applanation of the surface of the eye.

A disinfected or sterile disposable applanation prism is mounted on the Tonometer head at the end of the measurement arm and then placed against the cornea. The examiner then uses a cobalt blue filter to view two green semi circles, known as mires. The force applied to the Tonometer head is then adjusted using the rotating measurement drum connected to a variable tension spring until the inner edges of the green mires in the viewfinder meet. When an area of 3.06mm has been flattened, the opposing forces of corneal rigidity and the tear film are roughly approximate and cancel each other out allowing the pressure in the eye to be determined from the force applied.

The intraocular pressure is presented on the digital display.

The D-KAT is used in conjunction with commercially available Slit Lamps and can be used with the same mounting options as the predicate devices.

Calibration

During factory setup / calibration known pressures covering the measurement range are applied to the measurement arm using calibration bars verified using the calibration procedure outlined in the Tonometer standard ISO 8612:2009.

Calibration provides a relationship between the pressure applied to the measurement arm and the position of the rotating measuring drum. Linear interpolation is used between the calibration points.

It should be noted that whilst the D-KAT has a Digital read-out that can indicate decimal point measurement, it is not intended to imply higher accuracy. The D-KAT instrument has been validated to a measurement deviation of $\pm 0.49\text{mN}$ ($\sim 0.5\text{mmHg}$) or 1.5%, whichever is greater, in accordance with the above standard.

Software

The software uses information stored / programmed during the factory setup / calibration to monitor the position of the measurement arm against the position of the rotating measuring drum to determine the patients IOP, which is displayed to the user on the LED display.

5. Labelling and Intended Use

Instructions for use (IFU) for the applanation tonometer have been updated to incorporate the use of the digital interface.

The intended use of the Digital Keeler Applanation Tonometer (D-KAT) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

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

6. Materials Biocompatibility

With respect to material that comes into direct contact intentionally with the eye, there are no changes.

7. Cleaning and Disinfection

Cleaning instructions for the tonometer body and the recommended method for disinfecting applanation prisms remains unchanged.

Instructions have been provided in the Instructions for use.

8. Comparison of the device with the Predicate

The comparison table below summarizes the similarities and differences between both systems, with respect to safety and effectiveness, which are discussed in more detail in the following sections.

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Characteristic Features	Predicate Device - Keeler Applanation Tonometer (KAT)	Modified Device – Digital Keeler Applanation Tonometer (D-KAT)	Notes
Type	Manual contact Tonometer	Manual contact Tonometer	No change
Indication	Intraocular Pressure (IOP) measurement	Intraocular Pressure (IOP) measurement	No change
Units of measure	mmHg - millimetre of mercury	mmHg - millimetre of mercury	No change
Design	Slit lamp mounted manual dial	Slit lamp mounted manual dial	No change
Measurement Range	0-80mmHg	5-65mmHg	<p>A measurement range of 0 - 80mmHg is not a requirement for this device</p> <p>Device meets the requirements specified in the Tonometer standard ISO 8612:2009</p> <p>The modification does not affect the safety or effectiveness of the device</p>
Measurement technique	Applanation	Applanation	No change
Measurement Method	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	No change
Calibration	<p>Maintenance and calibration required</p> <p>Factory set</p> <p>Calibration arm assembly is</p>	<p>Maintenance and calibration required</p> <p>Factory set</p> <p>Calibration arm assembly is</p>	No change

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	supplied with each device to check calibration	supplied with each device to check calibration	
Intended use	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	No change
Mounting method on slit lamp	Fixed (R-Type) and Take-away (T-Type)	Fixed (R-Type) and Take-away (T-Type)	No change
Measurement deviation	0.49 mN or 1.5% of measurement value, whichever is the greater	0.49 mN or 1.5% of measurement value, whichever is the greater	No change
Power requirements	None required – device is mechanical	AA Battery to power digital display	Device has been tested to meet IEC 60601-1 Electrical Safety and IEC 60601-1-2 EMC requirements The modification does not affect the safety or effectiveness of the device
Software	None	Contains software	The software has been designed and developed in accordance with ISO 62304 Medical device software - Software life-cycle processes A Calibration (verification) Arm Assembly is supplied with each D-KAT to enable

			<p>the user to check the tonometer is in calibration.</p> <p>The modification does not affect the safety or effectiveness of the device</p>
Display	<p>Analogue scale - Direct reading from the dial (each division on dial of rotating measuring knob is equal to 0.2gmf (1.96mN)) which is multiplied by 10 by the user to calculate the pressure in mmHg</p>	<p>Numerical display - Direct reading of IOP in mmHg from display</p>	<p>Both devices generate a IOP in mmHg</p>

9. Performance and Safety

Verification tests have been carried out to confirm that the performance and safety aspects of the modified Digital Keeler Applanation Tonometer (D-KAT) are comparable with the Keeler Applanation Tonometer cleared for marketing under 510(k) K093445. The results demonstrated that the modified D-KAT was substantially equivalent in relation to performance, usability and safety to the aforementioned predicate device.

With respect to performance of the modified tonometer, bench testing using a balance system was carried to verify the measuring force was in accordance with Section A2 of ISO 8612:2009, Ophthalmic Instruments - Tonometers.

Usability tests have also been conducted by healthcare professionals, where comparisons were made against the predicate device (K093445).

In accordance with the Keeler Software Quality Plan, the software used in the modified D-KAT has been verified against design requirements and finally released, as required by IEC 62304 Medical device software - Software life cycle processes.

In addition to the above testing activities, Keeler has conducted assessment and/or testing to the following standards to further reinforce the safety and effectiveness of the modified D-KAT:

- AAMI ANSI 60601-1:2005 Medical Electrical Equipment-General requirements for safety and essential performance
- IEC 60601-1-2:2007 Medical Electrical Equipment-Electromagnetic compatibility-Requirements and tests
- ISO 15004-1:2006 Ophthalmic Instruments- Fundamental requirements and test methods Part 1: General requirements applicable to all ophthalmic instruments
- ISO 15223-1:2012 Medical Devices: Symbols to be used with medical devices labels, labelling and information to be supplied-general requirements
- ISO10993-1 Biological evaluation of medical devices: Evaluation and testing within a risk management process
- ISO14971:2007 Medical Devices-Application of risk management to medical devices

In all tests the modified device was in compliance with these FDA recognized standards.

10. Substantial Equivalence

The modified Digital Keeler Applanation Tonometer is considered to be substantially equivalent to the Keeler Applanation Tonometer described in the original 510(k) submission (K093445).



February 21, 2014

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

Keeler Instruments, Inc.
% Mr. Eugene R. VanArsdale
Marketing Manager
456 Parkway
Broomall, PA 19008-4295

Re: K133234

Trade/Device Name: Digital Keeler Applanation Tonometer (D-KAT)
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: January 6, 2014
Received: January 7, 2014

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. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

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Indications for Use Statement

510(k) Number (if known): K133234

Device Name: Digital Keeler Applanation Tonometer. (D-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 AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan C. Callaway -S
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