February 8, 2019

Keeler Instruments Inc.
Claudia Hill
Marketing Director
3222 Phoenixville Pike
Malvern, PA 19355

Re: K181143
Trade/Device Name: Keeler TonoCare Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: January 4, 2019
Received: January 7, 2019

Dear Claudia Hill:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181143

Device Name
Keeler TonoCare Tonometer

Indications for Use *(Describe)*
The Keeler TonoCare Tonometer is a hand-held, battery operated, non-contact tonometer intended to be used for measuring intraocular pressure (IOP) of the human eye with less than 3D in corneal astigmatism.

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
Keeler Non-Contact Tonometer Product Family

1. Submitter Contact Information

Company Name/Address:	Keeler Instruments Inc 3222 Phoenixville Pike, Building 50 Malvern, PA 19355 USA
CONTACT PERSON:	Claudia Hill Quality & Regulatory Manager
COMPANY PHONE NO.:	(610) 889 0200
COMPANY FAX NO.:	(610) 889 3233
DATE PREPARED:	April 23, 2018
MANUFACTURING LOCATION:	Keeler Ltd Clewer Hill Road, Windsor, Berkshire SL4 4AA. United Kingdom.
CONTACT PERSON:	Ms. Moria Zigman Senior Regulatory Officer
COMPANY PHONE NO.:	(44) 1753 857177
COMPANY FAX NO.:	(44) 1753 827145

2. Subject Device Information

DEVICE TRADE NAME:	Keeler TonoCare Tonometer
COMMON NAME:	Tonometer
DEVICE CLASS:	Class II
CLASSIFICATION PANEL:	Ophthalmic
PRODUCT CODE:	HKX
REGULATION NUMBER:	886.1930

3. Predicate Device Description

PRIMARY PREDICATE DEVICE:	Keeler Pulsair IntelliPuff Tonometer
510(K) REFERENCE:	K093298
SUBMISSION APPROVAL DATE:	10/12/2010
REFERENCE DEVICE:	Accutome Tonometer
510(K) REFERENCE:	K083377
SUBMISSION APPROVAL DATE:	07/27/2009

4. DEVICE DESCRIPTION:

The Keeler TonoCare Tonometer is designed to measure Intra Ocular Pressure (IOP) to aid in the screening and diagnosis of glaucoma without contacting the eye.

The Keeler TonoCare Tonometer has been designed using the same ergonomics as the predicate device described in 510(k) submission K093298. Both products consist of an air generation system in the form of a vacuum Diaphragm pump, an air reservoir, a solenoid valve, a light source and an opto-electronic platform which is used for position detection and IOP measurement.

The basic concept of operation is the same. The user positions the instrument close to the patient's cornea using a targeting system. As the user moves the instrument closer to the patient, the reflection off the cornea from the built-in light source increases until the predefined firing thresholds on the built-in photodiodes have been met. Once this condition has been met, a quantized puff of air is automatically projected toward the patient's cornea. As the cornea flattens due to the force of the puff of air, the light being reflected off of the cornea changes shape which in turn changes the profile of the light being reflected back onto the photodiodes. The rate of change of this reflection is monitored by the photodiodes and converted into intraocular pressure in units of mmHg by the on-board microprocessor.

The Keeler TonoCare Tonometer was launched into the European market in April 2018.

5. INDICATIONS FOR USE:

The Keeler TonoCare Tonometer is a hand-held, battery operated, non-contact tonometer intended to be used for measuring intraocular pressure (IOP) of the human eye with less than 3D in corneal astigmatism.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The Keeler TonoCare Tonometer and Keeler Pulsair IntelliPuff (K093298) are two variants of the same family of Keeler non-contact air impulse tonometers and their technological features are substantially equivalent with regards to the optical system, optoelectronic devices, electronics, pneumatic system, contained software, measurement technique, calibration technique, safety, effectiveness and intended use.

Previously not utilized in the Keeler Pulsair IntelliPuff, the TonoCare Tonometer allows for adjusted IOP calculations, as in the Accutome Tonometer (K083377), also referred to as CCT Correction. However, the accuracy of IOP measurements is known to be affected by variations and changes in corneal rigidity due to differences in corneal thickness, intrinsic structural factors or corneal refractive surgery. It is recommended that these factors are considered during IOP measurement. The biomechanical properties of an individual cornea may vary, resulting in changes of the relative stiffness or rigidity of the cornea and altering the measurement. Other factors to consider include corneal edema and other corneal abnormalities potentially affecting rigidity (e.g., keratoconus, corneal transplant, crosslinking) in addition to intrinsic structural factors and corneal refractive surgery.

Both the Keeler TonoCare Tonometer and Keeler Pulsair IntelliPuff (K093298) use different methods to generate and then deliver the puff of air with a known pressure time profile, but how the pressure in the chamber behind the puff tube is generated is immaterial to the measurement.

Most importantly the detection/viewing system has been deconstructed from the one system for both positioning and applanation detention functions in the Keeler Pulsair InteilliPuff (K093298) into two adjoining systems for the Keeler TonoCare Tonometer. This was done without changing the fundamental operating principles, in order to improve accuracy and repeatability as well as ease of use.

7. SUMMARY OF NON-CLINAL TESTS SUBMITTED:

Electrical safety and EMC testing were conducted on the Keeler TonoCare Tonometer and the device complies with IEC60601-1 and IEC60601-1-2 for EMC. Biocompatibility of the patient and user contacting materials was conducted in accordance with ISO10993-1. The risk management process was evaluated in accordance with ISO14971. Bench testing was conducted to demonstrate repeatability, reproducibility, and equivalency to the predicate device.

8. PERFORMANCE TESTING- CLINICAL PERFORMANCE

Repeatability and Reproducibility

Repeatability and reproducibility of TonoCare were assessed by measuring a manometrically controlled test eye.

Repeatability was measured using a single TonoCare device and a series of approximately 50 individual readings for each of 5 pressure values spaced evenly between the 5 to 50 mmHg working range. Readings were cross referenced with a reference pressure meter and a Pulsair Intellipuff device. Failed readings were rejected and averages of 3 subsequent readings were calculated to give a set of approximately 16 measurements at each of the 5 pressure values. Results demonstrate standard deviations ranging from 0.14 mmHg to 1.11 mmHg within the 5 to 50 mmHg pressure range respectively.

Reproducibility was assessed by analyzing measurements from three different TonoCare units by two different operators across 5 pressure values spaced evenly between the 5 to 50 mmHg working range. Two measurements (an average of 4 readings) at the 5 pressure values were taken for each of the six test cases (each operator using each of the three TonoCare devices). An Analysis of Variance (ANOVA) conducted on the data indicates a p-value of less than 0.05 and an R-square value of 98% or 99%, which signifies excellent reproducibility across operator and across devices.

Clinical Performance Data

Summary

The Keeler TonoCare Non-Contact Tonometer (NCT) was compared with the Perkins Applanation Tonometer (AT) in order to assess whether the TonoCare meets the requirements of ISO 8612 (comparable to ANSI Z80.10) in design compliance testing.

The Perkins AT uses the same basic principle as the Goldmann AT, namely, varying the force applied to applanate a fixed area of the cornea. Both instruments have an applanating ‘cone’ comprised of two prisms with apices joined together to apply an external force to the cornea to

indent and flatten its surface. There are several scientific articles referring to both instruments as reference standard tonometers and specifically the Perkins AT as the portable counterpart to the Goldmann AT (Wessels, I.F et al., 1990), (Carlos Garcia-Resua et al 2006), useful in domiciliary visits and for patients with mobility issues.

Two experienced observers acquired data from 144 qualifying eyes, measuring IOPs ranging from 7 mmHg – 23 mmHg in 50 participants and IOPs greater than 23 mmHg in 22 participants.

The results of the study show that the IOP measurements taken with the TonoCare NCT when compared to the reference Perkins tonometer (AT) do not exceed the ±5 mmHg tolerance in the three IOP ranges in 143 eyes with only 1 eye exceeding this tolerance for IOP measured >23 mmHg. This falls well below the requirement that no more than 5% of the paired differences between TonoCare and the reference tonometer should be outside the ±5 mmHg tolerance in the three IOP ranges.

Overall the mean of IOP differences between TonoCare and Perkins AT was <0.01 mmHg, with a median of -0.2 mmHg, indicating that the TonoCare NCT is equivalent to the applanation tonometer.

Methods

The study conducted was a single visit, single-center, non-randomized, non-masked paired crossover study. The study obtained IOP measurements on each eligible eye with the TonoCare and the reference standard Perkins tonometer.

Subjects were recruited according to the following inclusion and exclusion criteria.

Inclusion Criteria

- Subjects must be over 18 years of age
- Subjects must have healthy corneas with no contraindications for IOP measurements

Exclusion Criteria

- Subjects with only one functional eye
- Subjects with one eye having poor or eccentric fixation
- High corneal astigmatism (>3D)
- Corneal scarring, corneal surgery (including laser corneal surgery)
- Microphthalmosis
- Buphthalmos
- Contact lens wearers
- Dry eyes
- Lid squeezers
- Nystagmus
- Keratoconus
- Any other corneal or conjunctival pathology or infection

A total of 74 eligible participants were recruited, with 2 participants (2.7%) excluded. The reason for exclusion of two patients was due to excessive blinking or anxiousness resulting in the participant holding their breath. From the included 72 participants, IOP was measured in both eyes of all participants with TonoCare and Perkins AT, giving paired IOP measurements for a total of 144 eyes.

Results

Table 1 below gives summary of IOP characteristics of the group, showing measurements to have similar distributions.

Table 1: Summary of TonoCare and Perkins AT IOP measurements

	TonoCare	Perkins AT
N, eyes (patients)	144 (72)	144 (72)
Mean IOP, mmHg	21.2	21.2
Median IOP, mmHg	18.0	17.0
SD*, mmHg	7.9	8.0
Range, mmHg	11.8 to 46.3	11.0 to 41.0
IOP 7 to 16 mmHg, n (%)†	42 (29.2)	51 (35.4)
IOP 17 to 23 mmHg, n (%)†	58 (40.3)	49 (34.0)
IOP >23 mmHg**, n (%)†	44 (30.6)	44 (30.6)

No pairing structure is summarized in this table. *Standard deviation, †Only Perkins AT IOP categories are used for sub-group analyses, n is given in terms of eyes. **In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements

Table 2 below categorizes the absolute differences between TonoCare and Perkins AT IOP measurements >5 mmHg overall, and within 3 IOP subgroups. A difference greater than the tolerance of ±5 mmHg occurred in 1 (0.7%) eye out of 144, well below the maximum level of 5% according to the standard.

Table 2: Differences between TonoCare and Perkins AT IOP measurements >5 mm Hg overall, and within 3 IOP subgroups.

		IOP Group†			
		7 to 16 mmHg	17 to 23 mmHg	>23 mmHg**	Total
Difference*	Does not exceed ±5 mm Hg	51	49	43	143
	Exceeds ±5 mmHg	0	0	1	1
	Total	51	49	44	144

*IOP TonoCare – IOP Perkins AT, †Based on Perkins AT measured IOP

**In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements

Summary parameters of differences between pairs of TonoCare and Perkins AT IOP measurements are given in Table 3 below, for the full sample and by each IOP group. Overall the mean of IOP differences between TonoCare and Perkins AT was <0.01 mmHg, with a median of -0.2 mmHg. The 95% limits of agreement, based on the mean of IOP differences ±1.96 × the standard deviation of the IOP differences was -3.4 mmHg to +3.4 mmHg.

Table 3: Summary measures of IOP differences taken with TonoCare and Perkins AT measurements, summarized overall, and within 3 IOP subgroups.

	IOP Group†			
	7 to 16 mmHg (n=51)	17 to 23 mmHg (n=49)	>23 mmHg** (n=44)	Overall (n=144)
Mean	0.3	0.2	-0.6	0.0
Median	0.2	0.2	-0.9	-0.2
SD*	1.3	1.5	2.1	1.7
IQR§	-0.4 to 1.2	-0.8 to 1.0	-1.8 to 0.1	-1.0 to 1.0
Range	-3 to 4	-4.0 to 4.0	-3.8 to 6.2	-4.0 to 6.2

†Based on Perkins AT measured IOP, *Standard deviation, §Interquartile range

**In order to obtain measurements in this range, an inversion procedure was performed on a subset of participants while taking IOP measurements

It was concluded by the investigators that there are no clinically meaningful differences in IOP measurements among the tonometers, and that the TonoCare conforms to the standard as detailed.

Method used for calibration of test device

The TonoCare Tonometer unit was initially cross calibrated on several rubber eyes against Keeler Pulsair IntelliPuff (K093298).

In addition, a mini trial on volunteers have been conducted to further refine the calibration of the TonoCare Tonometer in order to minimize the error between the devices.

In regards to Perkins Goldman Applanation Tonometer- it has been acquired from Haag-Streit as the reference tonometer.

Accuracy of Measurements

Accurately assessing IOP is of great importance for the diagnosis, detection and possible need for referral and treatment of Glaucoma.

The Keeler TonoCare NCT was compared with the Perkins AT in order to assess whether the TonoCare meets the requirements of ISO 8612 (comparable to ANSI Z80.10) in design compliance testing.

Two experienced observers acquired data from 144 qualifying eyes, measuring IOPs ranging from 7 mmHg – 23 mmHg in 50 participants and IOPs greater than 23 mmHg in 22 participants.

The results of the study show that the IOP measurements taken with the TonoCare NCT when compared to the reference Perkins tonometer (AT) do not exceed the ±5 mmHg tolerance in the three IOP ranges in 143 eyes with only 1 eye exceeding this tolerance for IOP measured >23 mmHg. This falls well below the requirement that no more than 5% of the paired differences between TonoCare and the reference tonometer should be outside the ±5 mmHg tolerance in the three IOP ranges.

Overall the mean of IOP differences between TonoCare and Perkins AT was <0.01 mmHg, with a median of -0.2 mmHg, indicating that the TonoCare NCT is equivalent to the applanation tonometer.

9. SUBSTANTIAL EQUIVALENCE CONCLUSION:

Keeler TonoCare Tonometer is substantially equivalent to the predicate devices described in 510(k) K093298.

The clinical study conducted on TonoCare demonstrate the measurements obtained by the product are not significantly biased relative to those obtained by the established, gold standard Goldmann Tonometer and with no adverse customer feedback from sales of 510(k) K093298 units throughout the EU demonstrate that both products are safe and effective.

The Keeler TonoCare Tonometer and Keeler Pulsair IntelliPuff (K093298) are two variants of the same family of Keeler non-contact air impulse tonometers and their technological features are substantially equivalent with regards to the optical system, optoelectronic devices, electronics, pneumatic system, contained software, measurement technique, calibration technique, safety, effectiveness and intended use.

Previously not utilized in the Keeler Pulsair IntelliPuff, the TonoCare Tonometer allows for adjusted IOP calculations, as in the Accutome Tonometer (K083377), also referred to as CCT Correction

Most importantly the detection/viewing system has been deconstructed into two adjoining systems, without changing the fundamental operating principles, in order to improve accuracy and repeatability as well as ease of use.

Keeler Ltd. has determined that the variations to the Keeler Pulsair IntelliPuff (K093298) do not alter the system function, strength and stability or materials. Therefore, the Keeler TonoCare Tonometer is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness.