K093298

Keeler

Ophthalmic Instruments

DEC 10 2010

510(k) Summary
Keeler Non Contact Tonometer Product Family
7th October 2010

1. Submitter Contact Information:

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Contact Person:	Mr. Neil Atkins (QA and Production Engineering Manager).

2. Subject Device Information

Device Trade Name:	Keeler Pulsair IntelliPuff Tonometer Keeler Pulsair Desktop Tonometer
Common Name:	Tonometer
Class:	II
Classification Panel:	86
Product Code:	HKX
Regulation Number:	886.1930

3. Predicate Device Description

Predicate Device:	Keeler Pulsair 3000 Non Contact Tonometer
510(k) Reference:	K990257
Submission Approval Date:	25th March 1999

4. Device Description

The Keeler Pulsair Tonometer product family are non-contact tonometers and are used to measure intraocular pressure without contacting the eye to aid with the screening and diagnosis of glaucoma. The product family consists of the Pulsair Intellipuff (Hand Held device) and the Pulsair Desktop which is mounted on a desk. The Pulsair Intellipuff Tonometer has been designed using the same ergonomics as the predicate device described in 510(k) submission K990257 whilst the Pulsair Desktop Tonometer ergonomics have been adapted to suite the Desktop mounted market place. Both products use the same concept of measurement as the predicate device and contain many common components. All of the 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 quantised 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 Pulsair Intellipuff non-contact Tonometer was launched into the European market in April 2007.

The Pulsair Desktop non-contact Tonometer was launched into the European market in April 2009.

5. Indications for Use

The Pulsair IntelliPuff Non-Contact Tonometer is indicated for measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

The Pulsair Desktop Tonometer is indicated for measuring intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

6. Statement of Intended Use

The Pulsair Intellipuff and Pulsair Desktop tonometers are instruments that are intended to be used by trained healthcare professionals such as Ophthalmologists and Optometrists to aid with the screening of glaucoma. In isolation, the devices can not determine the presence of glaucoma but as part of a suite of screening instruments including Field screeners can help with screening and diagnosis.

The instruments can be used on all age groups but variation in corneal properties such as corneal thickness, corneal scaring and 'Dry Eye' could affect the performance of the instruments. It is recommended that all trained Healthcare professionals take these sources of variation into consideration when taking tonometric measurements of the eye.

There are no differences in Intended Use of the Pulsair Intellipuff and Pulsair Desktop Tonometer compared to the predicate device referenced in K990257.

7. Technology Characteristics and Equivalence to Predicate Device

Comparison of Non Contact Tonometer Technological Characteristics			
Criteria	**Predicate Device Keeler Pulsair 3000 Non-contact Tonometer (Re:510(k) K990257)**	**Subject Device 1: Keeler Pulsair IntelliPuff Tonometer**	**Subject Device 2: Keeler Pulsair Desktop Tonometer**
Type	Air Puff Non-Contact Tonometer	Air Puff Non-Contact Tonometer	Air Puff Non-Contact Tonometer
Illumination	6V, 6 Watt Halogen Filament Bulb	720nm, 1 Watt LED	720nm, 1 Watt LED
Measurement Range	7-50mmHg	5 to 50mmHg	5 to 50mmHg
Displayed scale	Direct in mmHg	Direct in mmHg	Direct in mmHg
Air Puff Generation	Vacuum Diaphragm Pump (Type:KNF 16961-86)	Vacuum Diaphragm Pump (Type:NPK 04)	Vacuum Diaphragm Pump (Type:NPK 04)
Pressure of Air Expelled from Tonometer	70mmHg	30mmHg & 70mmHg	30mmHg & 70mmHg
Power Source	Built into instrument-Mains powered	Keeler Power Supply (EP29-32777) 12V 2.5A	Keeler Power Supply (EP29-32777) 12V 2.5A
Input Voltage	100, 110, 120, 220, 240-Note ±10%	100 -240V (±10%)	100 -240V (±10%)
Input Frequency	50/60 Hz	50/60 Hz	50/60 Hz
Measurement Method	Opto-Electronic	Opto-Electronic	Opto-Electronic
Device Features	N/A	Forehead rest	Chin rest & Forehead rest
User Interface	Factory set	Factory set/User changeable	Factory set/User changeable
Printer	External	Built in	Built in
Data Display	LCD	Dot Matrix LED Display	Single line 16 character alphanumeric LCD display
Mounting Options	Wall and Desk Mountable	Wall and Desk Mountable	Desk mountable
Hand Unit Dimension	(H)265mm x (D)115mm x (W)40mm	(H)315mm x (D)150mm x (W)46mm	No hand Unit
Console Dimensions	(H)355mm x (D)305mm x (W)205mm	(H)260mm x (D)215mm x (W)220mm	(H)450mm x (D)435mm x (W)245mm
Hand Unit weight	0. 887Kg	0. 89kg	No Hand Unit
Console weight	7.280kg	2.465kg	16Kg
Length of umbilical cord	2.0m	2.0m	No umbilical cord
Software Level of Concern	Moderate	Moderate	Moderate
Reliance on Standards	Full clinical trial conducted in 1997 to ISO 8612:1997	Full Clinical trial conducted in 2007 to ISO 8612:2001	Clinical Equivalence of the Pulsair Desktop Tonometer to the Pulsair Intellipuff Tonometer demonstrated by a 28 eye three way comparison study with the Goldmann tonometer

8. Technological Equivalence to Predicate Device

A description of the main changes introduced in the Pulsair IntelliPuff and Pulsair desktop in relation to the FDA approved predicate device Keeler Pulsair 3000 Non-Contact Tonometer are as follows:-

- A sub-miniature Halogen bulb (note: visible light filtered out. Wave length of 680nm and above used) is replaced by a 720nm LED.
- Air puff control introduced i.e. softer puff used to obtain measurements on patients with IOP less than 23mmHg. This improves patient comfort.
- Photo sensors changed due to obsolescence of previously specified components.
- Smaller and quieter pump used to reduce environmental noise.
- Introduction of a user menu that allows the practitioner (user) to set the instrument to individual requirements.
- The instrument continuously compares measurements and when enough measurements have been taken, the instrument indicates this fact to the user via audible sound. This ensures that the patient does not receive more measurements than is absolutely necessary.

9. Technological Equivalence between Pulsair IntelliPuff and Pulsair Desktop

Keeler Pulsair IntelliPuff and Pulsair Desktop have similar technological features with regards to the optical system, optoelectronic devices, electronics, pneumatic system, contained software, measurement technique, calibration technique, safety, effectiveness and intended use.
Minor differences between Pulsair Desktop and Pulsair IntelliPuff are listed in the table below:

Pulsair IntelliPuff	Pulsair Desktop
Hand Held	Desk mounted & Joystick driven
Operator view through an eye piece	Operator view through a Camera and TFT Screen
One measurement displayed at a time	Can display up to four readings plus an average
Instrument goes to sleep mode on returning the hand unit to its cradle	Instrument sleeps after 5 minutes of inactivity
Left/right eye selection is manual	Left/Right eye selection is automatic

10. Calibration

The Pulsair Tonometer is an eye pressure measuring device. For this purpose, the system is equipped with an internal pressure transducer which is calibrated against an external pressure transducer, which in turn is calibrated against a known standard. The calibration process involves calibrating the optical and pneumatic systems of the instrument in various stages. The Keeler Pulsair IntelliPuff and Desktop are calibrated in the same manner as the predicate device Pulsair 3000 non-contact Tonometer.

11. Performance testing

Device performance: Risk management completed as per BS EN ISO 14971:2001(IntelliPuff) and BS EN ISO 14971:2007 (Desktop), which analyses and evaluates risks associated to the product and preventive actions to mitigate each risk. The Pulsair IntelliPuff and the Pulsair Desktop have been tested in accordance with BS EN ISO 15004 -2:2007 and are within the limits specified for Optical radiation Hazard. The Pulsair IntelliPuff and Desktop uses a medically approved Power supply (Keeler Ref: EP29-32777) which is compliant with BS EN 60601-1 and 60601-1-2. Pulsair Desktop and IntelliPuff have been tested for electrical safety to BS EN 60601-1 and Electromagnetic compatibility to BS EN 60601-1-2.

Software Development & Performance: Pulsair IntelliPuff and Pulsair Desktop software are derivatives of Pulsair 3000 non-contact Tonometer which was granted FDA approval in 1999. The algorithm for IOP calculation remains the same. Keeler sub-contracted the further development of this software for the Pulsair Intellipuff to an external development organisation. The organisation were employed to develop the functionality and usability of the existing software based on an initial Product Design Requirements Specification developed by Keeler for the Pulsair Intellipuff non contact Tonometer. They generated the subsequent documentation and conducted the various development activities associated with software and hardware development. All change control was managed by them until transfer into the Keeler QMS in 2007. All subsequent changes have been controlled under the Keeler Change Control Process. The software for the Pulsair Desktop non contact Tonometer was designed under Keeler design and development processes. The products have had numerous validation and verification activities conducted including bench and clinical testing. The results are included in this 510(k) submission.
The software for both the Pulsair Intellipuff and Pulsair Desktop are considered 'Moderate' level of concern.

Clinical Trial: A new independent clinical study was conducted on the Keeler Pulsair IntelliPuff Tonometer to show the design compliance of the Pulsair Tonometer against a reference Tonometer (Goldmann Tonometer). The study requirement for design compliance as specified in the ANSI Z80.10-2003 and ISO 8612:2001 stipulates that no more than 5% of the paired differences between the reference Tonometer and the Pulsair Tonometer should be outside the ±5mmHg tolerance in the three IOP ranges. The study showed that the readings obtained using the Pulsair Intellipuff were not significantly biased relative to those obtained using the Goldmann Tonometer, and the paired differences between the Intellipuff and Goldmann were within ±5mmHg for over 95% of the eyes tested. The Pulsair Intellipuff readings tended to fall slightly below the Goldmann readings at IOP's exceeding 30mmHg, but the difference was not clinically significant.

To demonstrate equivalence between the Pulsair Intellipuff Tonometer and the Pulsair Desktop Tonometer an additional small scale trial was conducted within a clinical environment on 28 eyes. The trial compared readings between the Pulsair Intellipuff, Pulsair Desktop and the Goldmann Tonometer. The results obtained from the trial demonstrate that the readings obtained using the Pulsair Desktop Tonometer were not significantly biased relative to those obtained using the Goldmann Tonometer, and the paired differences between the Desktop and Goldmann were within ±5mmHg for over 95% of the eyes tested. Further the results obtained from the trial demonstrate that the readings obtained using the Pulsair Desktop Tonometer were not significantly biased relative to those obtained using Pulsair Intellipuff, and the paired differences between the Desktop and Intellipuff were within ±5mmHg for over 95% of the eyes tested. We therefore conclude that the Pulsair Intellipuff and Pulsair Desktop tonometers are clinically equivalent.

Bench Testing: The performance of the Pulsair Desktop and Pulsair IntelliPuff Tonometer were tested under laboratory test conditions using an industry approved test set-up. The results of bench testing show that Keeler Pulsair IntelliPuff and Keeler Pulsair Desktop do produce repeatable and comparable measurements.

12. Conclusions

Based on the product verification and product validation activities we conclude that the Pulsair Intellipuff and Desktop Tonometers are substantially equivalent to the predicate device described in 510(k) K990257. The clinical trials conducted 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 units throughout the EU demonstrate that both products are safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Re: 510(k) K093298
Trade/Device Name: Keeler Pulsair Intellipuff Tonometer and Keeler Pulsair Desktop Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometers and Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: October 12, 2010
Received: October 14, 2010

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 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/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 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 know): K093298

DEC 10 2010

Device Name: Puslair Intellipuff and Pulsair Desktop non-contact Tonometer.

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The Pulsair Desktop Tonometer is indicated for measuring intraocular pressure without contacting the eye 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana L. Kaufman, M.A.

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

510(k) Number K093298