DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 19, 2016

Icare Finland Oy
Mr. Matti Tulikoura
Regulatory Manager
Ayritie 22
FI-01510 Vantaa, Finland

Re: K153694
Trade/Device Name: Icare Ic100
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKX, HKY
Dated: February 11, 2016
Received: February 12, 2016

Dear Mr. Tulikoura:

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" (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 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,

Kesia Alexander

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ic100

Indications for Use *(Describe)*

The Icare ic100 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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8.1 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

8.2 SUBMITTER NAME AND ADDRESS

Icare Finland Oy
Äyritie 22
Vantaa
Finland FI-01510

Contact: Matti Tulikoura (Regulatory Manager)
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Email: matti.tulikoura@icarefinland.com

Date Prepared: 12 April 2016

8.2 DEVICE NAME

Trade Name:	Icare ic100
Common/Usual Name:	Tonometer
Classification Name:	Tonometer and Accessories
Regulation No:	886.1930
Device Regulatory Class:	II
Review Panel:	Ophthalmic
Product Code:	HKY
	HKX
Premarket Notification (510(k)) Number:	N/A

8.3 PROPOSED MODIFICATION

The proposed modification described in this Traditional 510(k) covers the dimensional and graphical user interface (GUI) changes to the current Icare TA01i to allow for improved ergonomics and a larger OLED Display.

The Icare ic100 (TA011) uses the same operating principle found in the predicate device and in all rebound type tonometers.

The intended use of the Icare ic100 (TA011) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

8.4 DEVICE DESCRIPTION

The Icare ic100 (TA011) tonometer is a hand-held, battery operated device which measures intraocular pressure (IOP) without the need for topical anesthesia. The Icare ic100 (TA011) tonometer is fundamentally the same as the predicate Icare tonometer model TA01i (cleared by FDA under K063873). The measurement method, the IOP measurement algorithm and rebound technology (including disposable probe) are identical for both models. The Icare ic100 (TA011) tonometer utilizes the rebound method to measure intraocular pressure. A small (1.8 mm diameter), light (26.5 mg), sterile, single-use probe makes brief and gentle contact with the eye. The tonometer measures the deceleration of the magnetized probe and the rebound time during contact with the eye and calculates the IOP from these parameters. Deceleration of the probe is slower at low IOP compared to high IOP.

A single measurement sequence includes six measurements. After the six measurements are completed, the tonometer calculates the final IOP and the result is provided on the display.

METHOD OF OPERATION

Measurement Method

The IOP measurement algorithm is unchanged from the FDA cleared Icare tonometer model TA01i (K063873). Parameters from the signals produced by the probe momentarily contacting the eye (rebound parameters) are used to calculate an IOP-index. An embedded calibration table which was derived using Goldmann reference tonometer data is used to calculate an IOP value (in mmHg) based on the IOP-index. After the sixth measurement, the highest and lowest of the six IOP measurements are excluded and the remaining four are averaged to obtain the final IOP result which is displayed to the user.

Signal Processing

Identical to the predicate device, the Icare ic100 (TA011) tonometer records the speed of the probe upon initiation of a measurement sequence. The speed information is obtained from a coil, in which electrical signal is induced when the magnetized probe moves inside the coil.

The electrical signal is directly proportional to the speed of the probe. The analog signal obtained from the coil is amplified and digitized. Digitization is done using a microcontroller with embedded analog to digital converter. The digitized signal is stored and processed by a microcontroller. Intraocular pressure is calculated from the digitized speed data.

When the moving probe makes contact with the cornea, the probe decelerates at a rate which depends on the intraocular pressure. Deceleration of the probe at low IOP is slower compared to high IOP.

Calibration Procedure
As is the case for the predicate device, the design and principle of operation of the Icare ic100 (TA011) tonometer is such that maintenance calibration is not required. The tonometer does not include any mechanical or electrical parts subject to wear, excluding the probe base, which would cause an out of tolerance condition. Maintenance of the probe base is described in user manual.

Software

The Icare ic100 (TA011) Tonometer has embedded software utilizing a microcontroller. The software performs the following functions:

- Provides a user interface utilizing the user operable button and an OLED display to control the measurement cycle
- Provides control to LED Probe base light
- Controls the probe's movement
- Calculates the intraocular pressure from the probe speed during impact
- Handles possible error conditions, such as recognizing if probe didn't make contact with cornea or if the speed of the probe is abnormal
- Calculates the standard deviation of the measurements during the measurement cycle and instructs user to repeat the measurement if the variability is unacceptable
- Provides time setting to the internal clock
- Retrieves the serial number for identification of the device
- Stores measurement history in an external flash memory IC.

8.5 LABELING AND INTENDED USE

Instructions for Use (IFU) for the tonometer have been updated to reflect the design modifications.

The intended use of the Icare ic100 (TA011) as well as the method used by the clinician to obtain a reading remains unchanged by this modification.

Indications for Use:
The Icare ic100 tonometer is intended to be used for the measurement of intraocular pressure of the human eye.

8.6 MATERIALS BIOCOMPATIBILITY

There has been no change to the materials that contact the eye. Patient contact materials for the forehead rest have been evaluated based on ISO 10993-1 due to their transient contact with intact skin

8.7 CLEANING AND DISINFECTION

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

Instructions have been provided in the Instructions for Use.

8.8 COMPARISON OF THE DEVICE WITH THE PREDICATE

The comparison table below summarizes the similarities and differences between both systems.

		ICARE TA01i (K063873)	ICARE iC100 (TA011)
1.	Indication for Use	The Icare TA01i Tonometer is intended to be used for the measurement of intraocular pressure of the human eye.	Same
2.	Design	Hand-held microprocessor based	Same
3.	Measurement technique	Rebound tonometry	Same
4.	Calibration	No maintenance calibration required	Same
5.	Contact tip	Lightweight, disposable, single use, plastic probe (26.5mg)	Same
6.	Contact tip sterilization	Sterilized, disposable, single use	Same
7.	Force applied to eye during rebound measurement	8-16 mN	Same
8.	Display	4 digit LCD (2 digit reading)	1.50" OLED Display 128x128 Full color
9.	Range of measurement	7-50 mmHg (display range 1-99 mmHg)	Same
10.	Versatility	Tonometer must be oriented horizontally	Same
11.	Anesthesia required	No	Same
12.	Weight	5.47 oz. without batteries (155 g)	4.94 oz. without batteries (140 g)
13.	Dimensions	1.26" x 3.15" x 9.06" (32mm x 80mm x 230 mm)	1.14" x 3.74" x 8.46" (29mm x 95mm x 215mm)
14.	Power source	4 x 1.5 Volt AA batteries	Same

8.9 PERFORMANCE AND SAFETY

Verification tests, where applicable, have been carried out in accordance with ANSI Z80.10-2014 Ophthalmic Instruments - Tonometers to confirm that the performance and safety aspects of the modified tonometer are comparable with the Icare TA01i cleared for marketing under 510(k) K063873.

The software used in the Icare ic100 (TA011) has been verified against the requirements IEC 62304 Medical device software - Software life cycle processes.

The Icare ic100 (TA011) has also been evaluated against the requirements of IEC 60601-1 for electrical safety and to IEC 60601-1-2 for electromagnetic compatibility. In all tests the modified device was in compliance with these FDA recognized standards.

8.10 SUBSTANTIAL EQUIVALENCE

The Icare ic100 (TA011) Tonometer is considered to be substantially equivalent to the Icare TA01i described in the original 510(k) submission (K063873).