May 7, 2020

Icare Finland Oy
Hannes Hyvönen
Regulatory Affairs Manager
Äyritie 22
Vantaa, 01510
Finland

Re: K200966
Trade/Device Name: Icare HOME Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: April 7, 2020
Received: April 10, 2020

Dear Hannes Hyvönen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Ng
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K200966

Device Name
Icare HOME Tonometer

Indications for Use *(Describe)*
The Icare HOME tonometer is a prescription device intended as an adjunct to the routine clinical monitoring of intraocular pressure (IOP) of adult patients.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1.1 Submitter Name and Address

Icare Finland Oy
Äyritie 22
Vantaa, Finland FI-01510

Contact: Hannes Hyvönen
Phone: 358 9 8875 1150
Fax: 358 9 728 6670
Email: regulatory@icarefinland.com
Date prepared: May 4, 2020

1.2 Device Name

Trade Name:	Icare HOME tonometer
Common/Usual Name:	Tonometer
Classification Name:	Tonometer and Accessories
Regulation No:	21 CFR 886.1930
Device Regulatory Class:	II
Review Panel:	Ophthalmic
Product Code:	HKY

Premarket Notification 510(k) Number: K200966
This premarket notification type is Special 510(k).

1.3 Predicate Device

Icare HOME tonometer (type TA022), K163343
This predicate has not been subject to a design-related recall.

1.4 Indications for Use / Intended Use

"The Icare HOME tonometer is a prescription device intended as an adjunct to the routine clinical monitoring of intraocular pressure (IOP) of adult patients."

The intended use of the Icare HOME tonometer (type TA022) as well as the method used to obtain IOP measurement remain unchanged by this design modification.

1.5 Device Description

The Icare HOME tonometer is a home-use handheld, battery operated device that measures the intraocular pressure (IOP) without the need for topical anaesthesia. It is for prescription use only and to be used under the supervision of a healthcare professional. The device is intended to be used by patients at home.

The tonometer uses the rebound method. A small and light, sterile, single-use probe makes brief contact with the eye. The device measures the deceleration of the probe and the rebound time and calculates the IOP from these parameters. Deceleration of the probe is slower at low IOP compared to high IOP.

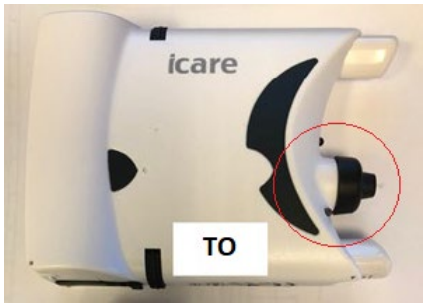
The measurement sequence includes six measurements. The probe moves to the cornea and back during every measurement. The tonometer stores information on every complete measurement sequence of six measurements. The stored information includes the calculated final IOP, time and date of the measurement, identification of the eye (right or left) and the quality level of the measurement (i.e. the standard deviation of the six individual measurements).

The measurement data can be uploaded to Icare CLINIC for further analysis using either Icare EXPORT (desktop application) or Icare PATIENT (mobile application). Icare CLINIC is a browser-based software designed for managing patient information and the IOP measurement data.

1.6 Comparison of Technological Characteristics with the Predicate Device

Comparison of the modified device to the cleared device is presented in the table below:

#	Characteristic	Modified device (subject of this 510k)	Cleared device (K163343)
1.	Product/Device Identification	Same	Icare HOME tonometer (type TA022)
2.	Intended Use / Indications for Use Statement	Same	IOP Measurement "The Icare HOME tonometer is a prescription device intended as an adjunct to the routine clinical monitoring of intraocular pressure (IOP) of adult patients."
3.	Intended Users	Same	Patients at home
4.	Design	Same	Handheld microprocessor based
5.	Calibration	Same	No maintenance calibration required
6.	Measurement range	Same	5-50 mmHg
7.	Measurement method	Same	Rebound tonometry
8.	Contact tip (probe)	Same	Lightweight, disposable, single use, plastic probe
9.	Contact tip sterilization	Same	Gamma-sterilized
10.	Anaesthesia required	Same	No
11.	Power supply	Same	2 x CR123 batteries

12.	Device dimensions and weight	Same	Dimensions: ~110mm x 80mm x 30mm Weight: ~150g
13.	Device Software Accessories	Difference, Icare LINK replaced with Icare CLINIC, Icare EXPORT and Icare PATIENT software	Icare LINK software
14.	Connectivity interface	Equivalent, added support for Android smartphone or tablet with USB OTG micro B male – micro B male cable and USB micro B to C adapter	USB
15.	User interface sounds	Equivalent, improved indication sounds (errors in 3kHz, all other indications remain the same 4kHz)	All indication sounds 4 kHz.
16.	Product appearance	Equivalent, narrow collar changes device appearance slightly 	

1.7 Performance and Safety Data

The device has been tested according to relevant FDA recognized consensus standards. The following performance and safety data of the modified device are provided in support of the substantial equivalence:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- ISO 15004-1:2006 Ophthalmic instruments – Fundamental requirements and test methods – Part 1: General requirements
- IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2006 + A1:2015 Medical device software - Software life-cycle processes (Device firmware and software level of concern: Class B)
- IEC 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
- IEC 62471:2006 Photobiological safety of lamps and lamp systems

There were no significant changes related to electromagnetic compatibility (EMC), sterilization or biocompatibility. Device and software risk analysis has been performed in accordance with ISO 14971 risk management standard. No clinical studies were performed to test this device modification.

1.8 Substantial Equivalence

The modified Icare HOME is substantially equivalent to the predicate device. The technological differences between the Icare HOME and its predicate device raise no new issues of safety and effectiveness. Performance and safety data demonstrate that the Icare HOME is as safe and effective as the predicate device.