January 25, 2022

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

Re: K211355
Trade/Device Name: iCare HOME2
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: December 17, 2021
Received: December 22, 2021

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211355

Device Name
iCare HOME2

Indications for Use *(Describe)*
The iCare HOME2 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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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
Email: regulatory@icare-world.com
Date prepared: January 18th, 2022

1.2 Device Name

Trade Name:	iCare HOME2
Type/model:	TA023
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: K211355
This premarket notification type is Traditional 510(k).

1.3 Predicate and Reference Device

Primary predicate: iCare HOME tonometer (type TA022), K200966
Reference device: iCare IC200 tonometer (type TA031), K190316.
The predicate device and the reference device have not been subject to a design-related recall.

1.4 Indications for Use / Intended Use

"The iCare HOME2 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 HOME2 tonometer is the same as the predicate device.

1.5 Device Description

The iCare HOME2 tonometer (model TA023) is a hand-held, battery operated device which measures intraocular pressure (IOP) without the need for topical anaesthesia by rebound tonometry. The tonometer is to be used by the patients themselves.

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 method, the IOP measurement algorithm and rebound technology (including disposable probe) are identical with the predicate device.

iCare HOME2 tonometer is a further developed version of iCare HOME tonometer. It features enhancements such as possibility to measure IOP in any angle between 0° and 90° (horizontal to supine patient position) and possibility for wireless measurement result transfer to mobile device or to PC. External design and user interface have been modified for better usability and ergonomics.

The measurement data can be uploaded to iCare CLINIC for further analysis using either iCare EXPORT (desktop application) or iCare PATIENT2 (mobile application). iCare PATIENT2 is a mobile app intended for transferring eye pressure measurement data from the iCare tonometer to the iCare CLINIC cloud service or an external system. The app displays the eye pressure measurement results and helps in glaucoma management. It is

indicated for use by healthcare professionals and patients. Measurement results can be transferred to iCare CLINIC with either through a Bluetooth connection or by connecting the USB C type connector to the device and mobile phone, depending on the user's mobile phone operating system.

1.6 Comparison of Technological Characteristics with the Predicate Device

Comparison of the subject device (iCare HOME2) to the predicate device (iCare HOME) and reference device (iCare IC200) is presented in the table below:

Characteristic	Subject device	Primary Predicate Device (K200966)	Reference Device (K190316)
Product Appearance			
Product/Device Identification	iCare HOME2 tonometer (Type: TA023)	iCare HOME tonometer (Type: TA022)	iCare IC200 Tonometer (Type: TA031)
Intended Use / Indications for Use Statement	Same as iCare HOME (K200966)	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."	IOP Measurement "The Icare ic200 tonometer is intended to be used for the measurement of intraocular pressure of the human eye."
Intended users	Same as iCare HOME (K200966)	Patients at home	Healthcare professionals
Measurement method	Same as iCare HOME (K200966) and iCare IC200 (K190316)	Rebound tonometry	Rebound tonometry

Measurement range	7-50 mmHg, substantially equivalent to iCare HOME (K200966) Same as iCare IC200 (K190316)	5-50 mmHg	7-50 mmHg
Versatility of Measurement position	Tonometer can be used in any angle between 0° (sitting, standing) and 90° (patient in supine position) Substantially equivalent as iCare HOME K200966, added supine position (similar to iCare IC200 K190316).	Tonometer must be oriented horizontally (0°, patient in sitting or standing position)	Tonometer can be used in any angle between 0° (sitting, standing) and 90° (patient in supine position)
Device Display	1.50" OLED display (same as to iCare IC200 K190316)	No display	1.50" OLED display
Automatic eye recognition system	Same as iCare HOME K200966	Yes	No
Design	Same as iCare HOME (K200966) and iCare IC200 (K190316)	Handheld microprocessor based	Handheld microprocessor based
Calibration	Same as iCare HOME (K200966) and iCare IC200 (K190316)	No maintenance calibration required	No maintenance calibration required
Contact tip (probe)	Same as iCare HOME (K200966) and similar to iCare IC200 (K190316)	Lightweight, disposable, single use, plastic probe (TP022)	Lightweight, disposable, single use, plastic probe (TP01s)
Contact tip sterilization	Same as iCare HOME (K200966) and iCare IC200 (K190316)	Gamma-sterilized	Gamma-sterilized
Anaesthesia required	Same as iCare HOME (K200966) and iCare IC200 (K190316)	No	No
Power supply	Substantially equivalent to iCare HOME K200966 (same as iCare IC200 K190316)	2 x 3V CR123 batteries	4 x 1,5V AA Alkaline LR6 batteries

Device dimensions and weight	Substantially equivalent Dimensions: 50 mm x 94 mm x 152 mm Weight: 205g (without batteries), 300g (with batteries)	Dimensions: 110mm x 80mm x 30mm Weight: 112g (without batteries), 150g (with batteries)	Dimensions: 43mm x 104mm x 214mm Weight: 165g (without batteries), 267g (with batteries)
Device Software Accessories	Substantially equivalent as iCare HOME (K200966), added iCare PATIENT2 as new SW accessory	iCare CLINIC, iCare EXPORT, iCare PATIENT, (also compatible with iCare PATIENT2)	iCare CLINIC, iCare EXPORT
Connectivity interface	USB 2.0 (USB type C) Substantially equivalent as iCare HOME (K200966) Bluetooth (Microchip RN4678 Module) Same as in iCare IC200 (K190316)	USB 2.0 (USB micro B)	Bluetooth (Microchip RN4678 Module)
User interface	Audio indications: Substantially equivalent to iCare HOME (K200966) and iCare IC200 (K190316)	Audio indications: Beeps for device too near or too far situation, and for other errors.	Audio indications: Beeps for device too near or too far situation, and for other errors.
	Graphical User Interface: Substantially equivalent to iCare HOME (K200966) and same as iCare IC200 (K190316)	Graphical User Interface: Indication lights panel	Graphical User Interface: OLED display
	Probe base light: Substantially equivalent to iCare HOME (K200966) and iCare IC200 (K190316). In addition, blue light indicates that the distance from the eye is too far.	Probe base light: Green: angle correct, device readiness Red: angle incorrect Blinking red: measurement error messages	Probe base light: Green: angle correct, device readiness Red: angle incorrect Blinking red: measurement error messages

1.7 Performance and Safety Data

The device has been tested according to relevant FDA recognized consensus standards. The following performance and safety data 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
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.
- 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
- ANSI Z80.36-2016 American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

There were no changes related to sterilization or biocompatibility. Device and software risk analysis has been performed in accordance with ISO 14971 risk management standard.

1.8 Bench Performance Testing

Accuracy of the iCare HOME2 tonometer was assessed in a bench test using a manometrically controlled artificial cornea. Manometric pressure was set by using reference tonometer iCare IC200, cleared in K190316.

Repeatability and accuracy testing completed with iCare HOME2 tonometer demonstrated high agreement with manometric pressure and reference tonometers (iCare IC200 and iCare HOME).

Reproducibility test completed with iCare HOME2 tonometer demonstrated high agreement with manometric pressure regardless of the device, operator, or the measurement angle.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "moderate" level of concern since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

1.9 Clinical Performance Testing

A clinical study was conducted to analyse the variability of the intraocular pressure (IOP) self-measurements with the iCare HOME2 tonometer in comparison to the variability of the IOP measurements with the reference tonometer (iCare IC200) over a wide range of IOP measurement values.

The performance data was obtained from a clinical study. The study was performed at East West Eye Institute, CA 90013, USA, and included 47 patients. All patients were found to be eligible for analysis. All the patients were either diagnosed glaucoma patients or 'glaucoma-suspects'. A random eye was selected as the study eye for each patient.

Safety: No adverse events (including corneal abrasions) were recorded in the study population.

Results: The mean paired difference and standard deviation (iCare HOME2 - iCare IC200) were 0.55 mmHg and 2.69 mmHg. The iCare HOME2's variability (difference of repeat measurements) for each patient was ~7.9% for all the IOP ranges.

Group	N	HOME2 Mean (SD)	Reference, IC200 Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference
≤ 16 mmHg	24	15.78 (2.86)	14.86 (2.9)	-0.93 (2.75)	-1.38, -0.48	-6.32, 4.46
>16 to <23 mmHg	13	20.17 (2.28)	19.56 (2.75)	-0.6 (2.66)	-1.2, -0.00	-5.81, 4.61
≥ 23 mmHg	10	23.88 (2.34)	24.33 (2.42)	0.44 (2.36)	-0.17, 1.05	-4.19, 5.07
Overall	47	18.72 (4.17)	18.17 (4.67)	0.55 (2.69)	-0.86, -0.23	-5.82, 4.72

1.10 Substantial Equivalence

The iCare HOME2 is substantially equivalent to the predicate device. The devices have the same or substantially equivalent technological characteristics and the iCare HOME2 raises no new issues of safety and effectiveness. Performance and safety data demonstrate that the iCare HOME2 is as safe and effective as the predicate device.