October 6, 2022

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

Re: K220852
Trade/Device Name: iCare IC200
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: September 5, 2022
Received: September 8, 2022

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 & Dental Devices
Office of Product Evaluation and Quality (OPEQ)
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)*
K220852

Device Name
iCare IC200

Indications for Use *(Describe)*
The iCare IC200 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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"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

Email: regulatory(at)icare-world.com

Date prepared: October 5th, 2022

1.2 Device Name

Trade Name:	iCare IC200
Type/model:	TA031
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: -

This premarket notification type is Traditional 510(k).

1.3 Predicate Device

Predicate device: iCare IC200 tonometer (type TA031), K190316.

The predicate device has not been subject to a design-related recall.

1.4 Indications for Use / Intended Use

"The iCare IC200 tonometer is intended to be used for the measurement of intraocular pressure of the human eye."

The intended use of the iCare IC200 tonometer remains unchanged by this design modification.

1.5 Device Description

The iCare IC200 tonometer (model TA031) 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 a healthcare professional.

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 IC200 tonometer can obtain IOP measurements in all angles between horizontal and supine directions. External design has not been modified. The user interface menu has been updated to contain a Quick Measure mode. The new Quick Measure feature is used to measure patient's IOP with fewer rebound measurements and faster measurement cycle. Quick Measure takes two or three rebound measurements; two if both results are within 2 mmHg and third if the difference between the first two measurements is greater than 2 mmHg.

1.6 Comparison of Technological Characteristics with the Predicate Device

Similarities of the subject device and the predicate device is presented in the Table 1 below:

Table 1 Similarities of the subject device and the predicate device

Characteristic	Modified device (subject of this 510k)	Cleared Device (K190316)
Product Appearance and materials	 Same	 Same
Product/Device Identification	Same	iCare IC200 Tonometer (Type: TA031)
Intended Use / Indications for Use Statement	Same	IOP Measurement "The iCare IC200 tonometer is intended to be used for the measurement of intraocular pressure of the human eye."
Intended users	Same	Healthcare professionals
Measurement method	Same	Rebound tonometry
Measurement range	Same	7-50 mmHg
Default measurement sequence	Same	Default measurement mode: 6 measurements, calculation of median IOP and standard deviation based on 4 measurements (highest and lowest excluded)
Versatility of Measurement position	Same	Tonometer can be used in any angle between 0° (sitting, standing) and 90° (patient in supine position)

Device Display	Same	1.50” OLED display
Automatic eye recognition system	Same	Not applicable
Design	Same	Handheld microprocessor based
Calibration	Same	No maintenance calibration required
Contact tip (probe)	Same	Lightweight, disposable, single use, plastic probe (TP01s)
Contact tip sterilization	Same	Gamma-sterilized
Anaesthesia required	Same	No
Power supply	Same	4 x 1,5V AA Alkaline LR6 batteries
Device dimensions and weight	Same	Dimensions: 43mm x 104mm x 214mm Weight: 165g (without batteries), 267g (with batteries)
Connectivity interface	Same	Bluetooth (Microchip RN4678 Module)
Electronics	Same	Inclination sensor, External Flash memory, Real time clock
Mechanics	Same	As described in K190316
User interface	Audio indications: Same	Audio indications: Beeps for device too near or too far situation, and for other errors.
	Graphical User Interface: Same	Graphical User Interface: OLED display
	Probe base light: Same	Probe base light: Green: angle correct, device readiness

		Red: angle incorrect, measurement not possible Blinking red: measurement error messages

Changes listed in Table 2 below.

Table 2 Differences of the subject device to the predicate device

Characteristic	Modified device (subject of this 510k)	Cleared Device (K190316)
Quick Measure Feature	Difference: a new Quick Measure feature added to measure patient's IOP with fewer rebound measurements and faster measurement cycle. -Quick Measure takes two or three rebound measurements; two if both results are within 2mmHg and third if the difference between the first two measurements is greater than 2mmHg.	Not applicable
User interface color	Graphical User Interface Colors: UI in Default measurement mode remains blue Difference: measurement sequence information and results in Quick Measure mode are shown in magenta color to differentiate from default measurement mode	Graphical User Interface Colors: Blue color
Alignment error indication	Alignment error remains enabled in default measurement mode. Difference: alignment error is disabled in Quick Measure mode.	Enabled in default measure mode
Device Software Accessories	Same during default measurement Difference: iCare CLINIC/EXPORT is not usable for Quick Measure results	iCare CLINIC, iCare EXPORT

Labelling	Difference: User manual is updated to include Quick Measure instructions and applicable warnings. Minor edits to quick guide and type label.	User manual, quick guide, type label

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
- 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)
- ANSI Z80.10:2014 Ophthalmic Instruments – Tonometers

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

Quick Measure performance data was obtained from a retrospective clinical data analysis in which Quick Measure function was retrospectively compared to the clinical data of iCare IC200. In the analysis Quick Measure met ANSI Z80.10:2014 (in accordance with

FDA´s extent of recognition) performance goals per GAT reference tonometer (see Table 3).

Table 3 Comparability Chart between IC200 Quick Measure and GAT, and Perkins, within IOP subgroups

Group	N (eyes)	Outside ±5 mmHg vs. GAT reference (Sitting)	Outside ±5 mmHg vs. Perkins reference (Supine)
GAT group = low ≤ 16 mmHg	44	0/44 (0.0 %)	0/44 (0.0 %)
GAT group = medium > 16 to < 23 mmHg	65	1/65 (1.5 %)	4/65 (6.2 %)
GAT group = high ≤ 23 mmHg	40	1/40 (2.5 %)	0/40 (0.0 %)

Accuracy of the iCare IC200 quick measure mode was assessed in a bench test using a manometrically controlled artificial cornea. Testing compared the new Quick Measure mode against the existing default measurement mode (same as in predicate device IC200), clinically validated subnormal reference tonometer (iCare IC200), and manometric pressure.

Repeatability and accuracy testing completed with iCare IC200 quick measure mode demonstrated high agreement with manometric pressure and reference tonometer used in default measurement mode (iCare IC200).

Reproducibility test completed with iCare IC200 quick measure mode 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 were 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 was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

1.8 Substantial Equivalence

The modified iCare IC200 including the Quick measure mode is substantially equivalent to the predicate device. The devices have the same or substantially equivalent technological characteristics and the iCare IC200 raises no new issues of safety and effectiveness. Performance and safety data demonstrate that the modified iCare IC200 is as safe and effective as the predicate device.