January 14, 2020

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

Re: K190316
Trade/Device Name: Icare ic200
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: December 4, 2019
Received: December 6, 2019

Dear Hannes Hyvonen:

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,

for Tieuvi Nguyen, Ph. D.
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)*
K190316

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.

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510 (K) SUMMARY

I. SUBMITTER NAME AND ADDRESS

Icare Finland Oy
Äyritie 22
Vantaa, Finland FI-01510

Contact: Hannes Hyvönen
Phone: 358 9 8775 1150
Fax: 358 9 728 6670
Email: regulatory@icarefinland.com
Date Prepared: January 9, 2020

II. DEVICE NAME

Trade Name:	Icare ic200
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: K190316

III. PREDICATE DEVICE

Icare ic100 tonometer (type TA011), K153694

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

IV. 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 (type TA031) as well as the method used by the clinician to obtain a measurement remain unchanged from the predicate tonometer Icare ic100 (TA011) by this design modification.

V. DEVICE DESCRIPTION

The Icare ic200 (TA031) tonometer is a hand-held, battery operated device, which measures intraocular pressure (IOP) without the need for topical anesthesia. The Icare ic200 tonometer measures the IOP by utilizing the rebound method, where a small (1.8 mm diameter), light (26.5 mg) probe makes brief contact with the eye. The Icare ic200 probes are sterile (gamma sterilized), single-use accessories of the device. All other accessories of the Icare ic200 are non-sterile and do not have direct patient contact.

Icare ic200 allows IOP measurement of patients in all positions between sitting position (direction of probe movement 0°) and supine position (direction of probe movement 90°).

Identical to the predicate device, the Icare ic200 (TA031) tonometer records the speed of the probe upon initiation of a measurement sequence. When the moving probe contacts the cornea, the probe decelerates at a rate which depends on the intraocular pressure. 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.

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. IOP measurement result can be transferred to printer or to a PC via Bluetooth® connection.

The measurement method, the IOP measurement algorithm and rebound technology (including sterile, single-use probe) of Icare ic200 are identical to the predicate device Icare ic100 (TA011, K153694).

Software

The Icare ic200 (TA031) 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 contact 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.
- Controls the device hardware based on device position (inclination)

In addition to the embedded software, the Icare ic200 includes an OTS (Off the Shelf) Bluetooth® module, which enables wireless communication.

Icare proprietary software Icare EXPORT and Icare CLINIC are designed to work with the Icare ic200 as software accessory. Icare EXPORT is intended for transferring measurement data from Icare tonometers into the Icare CLINIC software's database. Icare CLINIC performs the following functions:

- Stores measurement data received from Icare devices
- Shows and prints charts based on the measurement data
- Exports measurement data from Icare CLINIC to external systems
- Imports measurement data from external systems
- Maintains patient database and measurement history

Calibration

As is the case for the predicate device, the design and principle of operation of the Icare ic200 (TA031) tonometer is such that maintenance calibration is not required. The tonometer does not include any mechanical or electrical parts subject to wear, which would cause an out of tolerance condition. Only the probe base, which as an accessory, can be replaced or cleaned by user as instructed in the Instructions for Use.

Environment of use

The Icare ic200 tonometer is intended to be used in professional healthcare environment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological principle of both the subject and predicate devices is rebound tonometry. The table below summarizes the similarities in technological characteristics of the new device compared to the predicate device.

		Icare ic100 (TA011, K153694)	**Icare ic200 (TA031, K190316)**
1.	Indication for Use	The Icare TA011 Tonometer is intended to be used for the	The Icare TA031 Tonometer is intended to be used for the measurement

		measurement of intraocular pressure of the human eye.	of intraocular pressure of the human eye.
2.	Design	Hand-held microprocessor based	Same
3.	Measurement technique	Rebound tonometry, result calculated based on IOP measurement algorithm	Same
4.	Calibration	No maintenance calibration required	Same
5.	Contact tip (probe)	Lightweight, disposable, single use, plastic probe (26.5mg)	Same
6.	Contact tip sterilization	Gamma-sterilized	Same
7.	Force applied to eye during rebound measurement	8-16 mN	Same
8.	Display	1.50" OLED Display 128x128 Full color	Same
9.	Range of measurement	7-50 mmHg (display range 1-99 mmHg)	Same
10.	Measurement accuracy (bench)	Accuracy: ± 1.2 mmHg (IOP ≤ 20 mmHg) Accuracy: ± 2.2 mmHg (IOP > 20 mmHg) Coefficient of variation CV < 8 %	Same
11.	Anesthesia required	No	Same
12.	Power source	4 x 1.5 Volt AA batteries	Same

The following technological differences exist between the subject and predicate devices:

		Icare ic100 (TA011, K153694)	**Icare ic200 (TA031)**
1.	Device structure	Display and navigation buttons on the side	Display and navigation buttons towards the user, on the back side of the device
		Weight 4.94 oz. without batteries (140 g)	Weight 5.82 oz. without batteries (165 g)
		Dimensions 1.14" x 3.74" x 8.46" (29mm x 95mm x 215mm)	Dimensions 1.69” x 4.10” x 8.43” (43mm x 104mm x 214mm)

2.	Versatility of measurement direction	Tonometer must be oriented horizontally (0°, patient in sitting position)	Tonometer can be used in any angle between 0° (sitting) and 90° (patient in supine position)
3.	Wireless data transfer	Not available	Wireless measurement result transfer to a printer or PC via Bluetooth® connection.
4.	Graphical user interface	Includes all basic functions.	Includes all basic functions similar to ic100, and possibility to add eye side information and patient ID and to select Bluetooth® connection.

The primary modification within this 510(k) submission is the improvement in versatility of the measurement direction (sitting and supine). Modifications of external device structure and user interface are secondary modifications, which support this primary modification and improve the usability of the device.

Wireless measurement result transfer via Bluetooth® is a state-of-the-art feature, which has been added as a separate option that can also be disabled. Wireless connection doesn't affect the clinical use, measurement software, primary result display or any features related to the clinical safety and effectiveness of the device.

VII. PERFORMANCE TESTING

The following performance testing has been conducted to confirm that the performance and safety aspects of the modified tonometer Icare ic200 are substantially equivalent with the Icare ic100 cleared for marketing under 510(k) K153694.

Software Verification and Validation Testing

The software used in the Icare ic200 (TA031) is based on predicate device Icare ic100 software and the modifications have been developed and maintained per the requirements IEC 62304 Medical device software - Software life cycle processes. Software verification and validation testing were conducted, and documentation was generated 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 to cause "moderate" level of concern, since a failure or latent flaw in the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care.

Bluetooth® software (OTS) included in Icare ic200 was considered to cause "minor" level of concern, since the software does not influence the intended use or clinical functions of the device and the measurement result display enabled by the Bluetooth® is additional to the primary measurement result display method.

The Icare CLINIC and EXPORT software are accessories to ic200 and therefore they are also considered to have "moderate" level of concern. They have been developed and maintained per the requirements of IEC 62304 standard and software verification and validation testing has been conducted and documented per FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Icare ic200 tonometer. The device complies with the IEC 60601-1standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Bench performance testing

Icare ic200 tonometer performance in IOP measurement was compared to predicate device Icare ic100 tonometer performance. The testing was performed with a simulated IOP model, which was also used during the original predicate device submission (K153694).

- Icare ic200 met the predetermined acceptance criteria for accuracy and bias over the measurement range ensuring substantial equivalence to the previously cleared Icare ic100 tonometer.
- Repeatability of the Icare ic200 tonometer was assessed in bench test. Test was done by measuring a manometrically controlled test cornea. Test pressures (7, 10, 20, 30, 40 and 50 mmHg) covered the specified measurement range of the Icare ic200 tonometer. To assess repeatability, 10 measurements were performed with the test tonometer in three different angles (0, 45 and 90 degrees).

  Icare ic200 tonometer demonstrated an agreement with true manometric pressure, R- squared values being over 99.7 %, regardless the angle of measurement (0, 45 or 90 degrees). On average, the Icare ic200 tonometer underestimated the pressure by 0.33 mmHg with respect to true manometric pressure, standard deviation being 0.82 mmHg.
- Reproducibility was assessed by test in which two operators performed three measurements with three different ic200 units in each measurement setup, resulting 162 measurements per operator. The mean difference between operators was 0.10 mmHg with standard deviation of 0.98 mmHg. The R-squared value in regression analysis was over 99.5%, which indicates high reproducibility across the operators and across the devices.

Please be advised that bench testing conditions do not cover all the error sources within a clinical setting and thus higher variability is expected in clinical use.

Clinical performance testing

Clinical study was to compare the agreement and precision of the intraocular pressure (IOP) results measured by the Icare ic200 tonometer device with the Goldmann Applanation Tonometer (GAT) reference device per ANSI Z80.10:2014 "Ophthalmic Instruments – Tonometers" standard (in accordance with FDA´s extent of recognition).

In addition, GAT and Tonopen Avia were compared with Icare ic200 in the sitting position and Tonopen Avia and Perkins in the supine position. Possible individual patient discomfort and potential device complications or adverse events were recorded. No adverse events (including corneal abrasions) were reported in this study.

Per the ANSI Z80.10 standard the differences between ic200 and GAT measurements overall and within three IOP subgroups are summarized in Table 1 below.

Table 1. Differences between ic200 and GAT, overall and within IOP subgroups

Group	N (eyes)	Outside ±5 mmHg
GAT group = low ≤ 16 mmHg	45	0/45 (0.0%)
GAT group = medium > 16 to <23 mmHg	67	2/67 (3.0%)
GAT group = high ≥ 23 mmHg	40	0/40 (0.0%)
Overall	152	2/152 (1.3%)

The descriptive statistics (n, Mean, SD, Median, Min, Max) for the IOP measurements from ic200, GAT and Tonopen Avia in sitting position are summarized in Table 2 below.

Table 2. Summary of IOP measurements ic200, GAT and Tonopen Avia in sitting position

	ic200	GAT	Tonopen Avia
n (eyes)	152	152	152
Mean IOP (mmHg)	20.44	19.88	20.26
SD (mmHg)	5.82	5.49	5.68
Median (mmHg)	20.30	20.00	20.50
Min (mmHg)	10.8	10.0	10.5
Max (mmHg)	44.6	43.0	42.5

The descriptive statistics for the IOP measurements from ic200, Tonopen Avia and Perkins in supine position are summarized in Table 3 below.

Table 3. Summary of IOP measurements ic200, Tonopen Avia and Perkins in supine position

	ic200	Tonopen Avia	Perkins
n (eyes)	152	152	152
Mean IOP (mmHg)	21.01	20.50	20.15
SD (mmHg)	5.59	5.66	5.61
Median (mmHg)	21.38	20.50	20.50
Min (mmHg)	10.2	11.5	10.5
Max (mmHg)	41.9	42.0	40.5

The results of the study demonstrated that Icare ic200 is safe and performed as intended and conformed with the ANSI Z80.10 standard compared to GAT.

Conclusions

The overall performance testing (bench and clinical) demonstrated that the Icare ic200 provides equivalent performance as the predicate device Icare ic100.

VIII. SUBSTANTIAL EQUIVALENCE

The Icare ic200 tonometer uses the same operating principle found in the predicate device and in all rebound type tonometers. The intended use of the Icare ic200 as well as the method used by the clinician to obtain a measurement remain unchanged by the modifications. The technological comparison demonstrates that the use of Icare ic200 does not raise additional questions of safety and effectiveness.

In conclusion, it has been demonstrated that the Icare ic200 (TA031) tonometer is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization (of probes), operating principle, performance and intended use/ indication for use as the previously cleared Icare ic100 tonometer described in the original 510(k) submission (K153694).