September 27, 2024

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

Re: K241447
Trade/Device Name: iCare ST500 (TA04)
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY, HKX
Dated: August 20, 2024
Received: August 20, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Alexander Beylin -S 2024.09.27 12:03:30 -04'00'

for 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)*
K241447

Device Name
iCare ST500 (TA04)

Indications for Use *(Describe)*
The iCare ST500 tonometer is a device intended to be used for the measurement of the intraocular pressure of the human eye.
The iCare ST500 tonometer is intended to be used by healthcare professionals.

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 Contact Details

Applicant Name: Icare Finland Oy

Applicant Address: Äyritie 22 Vantaa 01510 Finland

Applicant Contact Telephone: 358 9 8875 1150

Applicant Contact: Mr. Hannes Hyvönen

Applicant Contact Email: regulatory@icare-world.com

Prepared on: September 25th, 2024

1.2 Device Name

Device Trade Name:	iCare ST500 (TA04)
Common Name:	Tonometer and accessories
Classification Name:	Tonometer, Manual
Regulation Number:	886.1930
Product Code(s):	HKY, HKX

Premarket Notification 510(k) Number: K241447

This premarket notification type is Traditional 510(k).

1.3 Legally Marketed Predicate Devices

Predicate #: K220852

Predicate Trade Name (Primary Predicate is listed first): iCare IC200 (TA031)

Product Code: HKY

1.4 Device Description Summary

The iCare ST500 tonometer is based on a patented, induction-based rebound method, which allows intraocular pressure (IOP) to be measured by a healthcare professional accurately, rapidly and without an anesthetic. The iCare ST500 tonometer measures a

patient's IOP while he or she is in an upright (sitting) position. It is attached to a slit lamp with the ST500 Adapter, making it easy to use during a standard eye exam. This tonometer is designed only for use with a slit lamp not as a handheld device. The tonometer is compatible with most of the common slit lamp models on the market.

The tonometer system consists of the iCare ST500 tonometer (together with ST500 Remote and ST500 Adapter, ST500 SmartCradle and a medical power supply used with ST500 SmartCradle), and a compatible printer and slit lamp.

With the iCare rebound measurement method, a miniature, lightweight, single-use probe is launched in a direction perpendicular to the surface of the center of the cornea of the eye. The probe is composed of a medical grade plastic tip and a metal shaft. The metal shaft is magnetized prior to the measurement. During the measurement, the probe can be considered to act like a moving magnet that induces an electric signal in the surrounding coil allowing for a highly accurate measurement of the probe’s motion. After launching, the probe briefly contacts the cornea and bounces back. The tonometer records multiple parameters covering the motion of the probe, including deceleration, and rebound time. Using a proprietary algorithm, the device can calculate the eye’s IOP.

The displayed IOP reading is derived from the results from a sequence of six individual probe rebounds. The displayed IOP measurement is also stored in the tonometer’s memory for later retrieval.

The iCare ST500 tonometer has a rechargeable battery and can be charged in the ST500 SmartCradle powered by a medical power supply. The tonometer can be operated by using the buttons on the tonometer or by using the wireless battery-operated ST500 Remote control.

1.5 Intended Use / Indications for Use

The iCare ST500 tonometer is a device intended to be used for the measurement of the intraocular pressure of the human eye.

The iCare ST500 tonometer is intended to be used by healthcare professionals.

1.6 Indications for Use Comparison

Indications of use statement is equivalent to the predicate device (see Table 1 below).

1.7 Technological Comparison

The new iCare ST500 tonometer features the same or equivalent technology as in the predicate device iCare IC200 (K220852) such as:

• Automated measurement sequence, where full measurement sequence can be completed by keeping the measurement button pressed down.

• Wireless connectivity with Bluetooth connection to printer and remote control.

• The Quick Measure feature measures the patient's IOP with fewer rebound measurements and a faster measurement cycle.

Differences with respect to the predicate device iCare IC200 (K220852) are:

• Mounted on a slit lamp with the ST500 adapter, allowing the measurement to be performed only in horizontal (sitting) position.

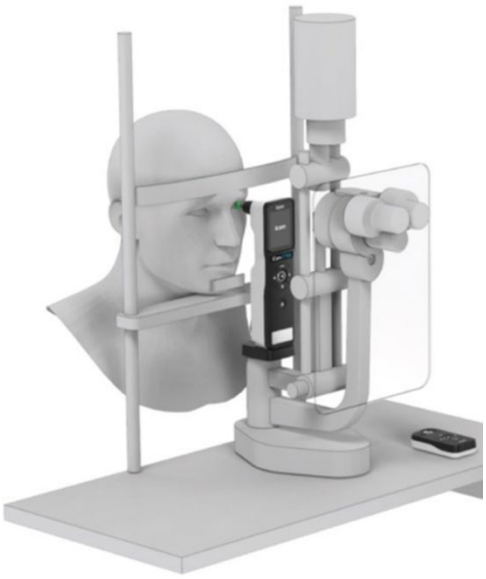
• Automatic eye side recognition system, an automatic IR-based eye side detection and control functionality. Equivalent to reference device iCare HOME2 (K211355).

• Probe applicator, a funnel shaped applicator used to ease the loading of the probe. Equivalent to reference device iCare HOME2 (K211355).

• Remote control, the tonometer can be operated by using the buttons on the tonometer or by using the wireless battery-operated ST500 Remote control.

• Rechargeable battery, the iCare ST500 tonometer has a rechargeable battery and can be charged in the ST500 SmartCradle powered by a medical power supply.

Table 1 – Predicate Comparison Table

Characteristic	Subject device (K241447)	Predicate Device (K220852)
Product Appearance		
Product/Device Identification	iCare ST500 tonometer (Type: TA04)	iCare IC200 Tonometer (Type: TA031)
Intended Use / Indications for Use Statement	Equivalent "The iCare ST500 tonometer is a device intended to be used for the measurement of the intraocular pressure of the human eye. The iCare ST500 tonometer is intended to be used by healthcare professionals."	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	Equivalent, Default measurement mode: 6 measurements are averaged	Default measurement mode: 6 measurements, calculation of median IOP and standard deviation based on 4 measurements (highest and lowest excluded)

Measurement positions	Equivalent Tonometer must be oriented horizontally (0°, patient in sitting position), no supine position measurement possibility, only for slit lamp use not as a handheld device	Tonometer can be used in any angle between 0° (sitting, standing) and 90° (patient in supine position)
Device Display	Equivalent, 240 x 320 RGB LCD display	128 x 128 full color OLED display
Automatic eye recognition system	Difference, but equivalent to reference device iCare HOME2 (K211355)	No
Design	Equivalent, Slit-lamp mounted microprocessor based	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	Difference, Li-ion rechargeable battery, 3,6 V / 2200-2400 mAh (not replaceable by the user)	4 x 1,5V AA Alkaline LR6 batteries
Device dimensions and weight	Equivalent, Dimensions: 46 x 70 x 181 mm (L x W x H) Weight: 226g (including internal power supply)	Dimensions: 43 mm (W) * 104 mm (H) * 214 mm (L) Weight: 165g (without batteries)
Connectivity interface	Equivalent, Bluetooth (ANNA-B112 Module) Difference, Near Field Communication (NFC)	Bluetooth (Microchip RN4678 Module)
User interface	Audio indications:	Audio indications:

	Equivalent	Beeps for device too near or too far situation, and for other errors.
	Graphical User Interface: Equivalent, 240 x 320 RGB LCD display	Graphical User Interface: 128 x 128 full color OLED display
	Probe base light: Green: same Red: same Blinking red: same	Probe base light: Green: angle correct, device readiness Red: angle incorrect, measurement not possible Blinking red: measurement error messages

The iCare ST500 has the same basic operation principle, underlying technology (rebound tonometry) and device materials as the predicate device. The device performance is substantially equivalent.

1.8 Non-Clinical Performance Testing

The device has been tested based on FDA recognized consensus standards. The following information shows its performance and safety, supporting its substantial equivalence.:

-ISO 15004-1 Second edition 2020-5 (10-123)

-ANSI Z80.36-2021 (10-130)

-IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION (19-49)

-ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] (19-36)

-IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION (5-132)

-ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) (5-129)

-ANSI AAMI IEC 62304:2006/A1:2016 (13-79)

-ISO 10993-1:2018 (2-258)

-ANSI Z80.10-2014 (10-96)

There were no changes related to sterilization (of probes). Device and software risk analysis has been performed in accordance with ISO 14971:2019 risk management

standard. Device firmware and software level of concern was Class B (Basic Documentation).

Summary of bench testing performed is presented below:

The accuracy and repeatability of the Icare ST500 tonometer was assessed in a bench test. The test was done by measuring manometrically controlled test corneas. To assess accuracy and repeatability, measurements were performed with the test tonometer using Default Measure and Quick Measure.

Icare ST500 met the predetermined acceptance criteria for accuracy and repeatability over the measurement range ensuring substantial equivalence to the previously cleared Icare IC200 (K190316) tonometer both for Default Measure and Quick Measure.

For repeatability with Default Measure, the highest standard deviation was 0.44 mmHg (CV 1.1 %). With Quick Measure, the highest standard deviation was 0.78 (CV 1.9%).

Reproducibility was assessed in a test in which two operators performed three measurements with three different ST500 units. Across all the three iCare ST500 units, the mean differences between the operators were -0.12 mmHg and -0.02 mmHg with a standard deviations of 0.75 mmHg and 0.91 mmHg for Default Measure and Quick Measure, respectively. The R-squared value in regression analysis was 99.8% for Default Measure and 99.7% for Quick Measure, which indicates high reproducibility across the operators for both Default Measure and Quick Measure of iCare ST500 tonometer.

The iCare ST500 has two measurement modes: Single and Series. In the Single Mode, the probe is shot every time the measurement button is pressed. In the Series Mode, the measurement button is pressed and held, and the probe is shot consecutively until the measurement is finished or the measurement button is released. The performance of ST500 is not affected the mode used.

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.

1.9 Clinical Performance Testing

The clinical study was made for iCare ST500 tonometer according to ANSI Z80.10:2014 (in accordance with FDA´s extent of recognition). See Table 2 below.

Table 2 – iCare ST500 1st measurement vs. GAT mean

Mean GAT – 1st ST500				
	≤ 16 mmHg	16 – 23 mmHg	≥ 23 mmHg	Total
Number of eyes	59	57	40	156
Number of outlier	0	2	2	4
Percentage of outliers	0.0%	3.5%	5.0%	2.6%

There were 165 subjects enrolled in the study of which 156 had at least one eligible eye. The measurements were made with iCare ST500 and reference tonometers iCare IC200 and GAT. In case both subject's eyes were eligible, the eye with higher GAT reference pressure was used in the analysis (so the number of eyes included in the analysis was 156). The population of the study consisted of subjects having an appointment to the investigational site and from subjects recruited using a study announcement.

On average iCare ST500 underestimated IOP by 0.21 mmHg compared to GAT. The IOP groups (per standard) were low (≤ 16 mmHg), medium (> 16 to < 23 mmHg) and high (≥ 23 mmHg). There was underestimation in low (0.20 mmHg) and medium (0.49 mmHg) IOP groups and overestimation in medium (0.18 mmHg) IOP group. Regression analyses confirmed that iCare ST500 results correlate well compared to GAT results: the slope and the squared Pearson coefficient of correlation were close to 1 (1.03 and 0.89, respectively). In conclusion, iCare ST500 met the requirements of ANSI Z80.10-2014.

1.10 Conclusions

Based on the nonclinical and clinical tests iCare ST500 tonometer is safe and performed as intended when used according to its indications for use and in accordance with its labeling. It performs as well as the legally marketed predicate device.