DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 21, 2017

Icare Finland Oy
% Mr. Mark DuVal
President and CEO
DuVal & Associates, P.A.
1820 Medical Arts Building,
825 Nicollet Mall
Minneapolis, MN 55402

Re: K163343/S001
Trade/Device Name: Icare Home tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKX
Dated: February 6, 2017
Received: February 7, 2017

Dear Mr. DuVal:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163343

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.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUMMARY PREPARED: March 8th, 2017

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

APPLICANT: Icare Finland Oy
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01510 Vantaa, Finland

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NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

TRADE NAME:	Icare HOME tonometer
COMMON NAME:	same
CLASSIFICATION NAME:	Tonometer, Ac-Powered
DEVICE CLASSIFICATION:	Class II under 886.1930
PRODUCT CODE:	HKX

PREDICATE DEVICE:	• Primary Predicate Device
	  o Icare TA01i Tonometer (K063873)
	• Secondary Predicate Device
	  o Goldmann-type Applanation Tonometer, Haag-Streit AT900 (K981432)

BRIEF DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Icare HOME Tonometer is a home-use handheld, battery operated device. The Icare HOME tonometer technology is based on the previously cleared Icare tonometer model TA01i (K063873), which has been commercially distributed in the United States, Europe and many other countries worldwide. The measurement method, the measurement algorithm and technology of the two models are identical and both models use the same disposable probe tip.

The Icare HOME tonometer utilizes the rebound method to measure intraocular pressure. A small (1.8 mm diameter), light (26.5 mg), sterile, single-use probe tip makes brief and

gentle contact with the eye. The device measures the deceleration of the magnetized probe and the rebound time during contact with the eye and calculates the IOP from these parameters. Deceleration of the probe is slower at low IOP compared to high IOP.

A single measurement sequence includes six measurements for both measurement modes. The probe moves to the cornea and returns to the neutral position during each of the six measurements. After the six measurements the tonometer calculates the final IOP and stores it with other information in the tonometer's memory, including date, time, eye identification (right or left) and measurement quality i.e., the standard deviation of the six individual measurements.

The Icare HOME Tonometer can record over one thousand measurement results. The physician can transfer this recorded measurement information to a computer through a USB cable.

INDICATION FOR 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.

PREDICATE DEVICE COMPARISON TABLE

TABLE 1. ICARE HOME TONOMETER COMPARED TO PREDICATE DEVICES.

	ICARE HOME	ICARE TA01i (K063873)	GOLDMANN-TYPE APPLANATION TONOMETER, HAAG-STREIT AT900 (K981432)
Intended Use	IOP measurement	IOP measurement	IOP measurement
Intended Users	Patients at home	Health care professionals in a clinical environment	Health care professionals in a clinical environment
Indications for Use Statement	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 Icare TA01i Tonometer is intended to be used for the measurement of intraocular pressure of the human eye.	The Goldman manual tonometer is an appliance that serves to measure intraocular pressure, according to the Goldman method. The measuring of the pressure requires to maintain a uniform applanation of the surface of the cornea. It is specially indicated in glaucoma disease.

	ICARE HOME	ICARE TA01i (K063873)	GOLDMANN-TYPE APPLANATION TONOMETER, HAAG- STREIT AT900 (K981432)
Design	Handheld microprocessor based	Handheld microprocessor based	Slit lamp mounted, purely mechanical, manual dial
Measurement range	5-50 mmHg	7-50 mmHg	0-80 mmHg
Contact interface	Sterilized, single use plastic probe, cornea	Sterilized, single use plastic probe, cornea	multiuse plastic prism, Cornea
Measurement Method	Rebound	Rebound	Applanation
Measurement Algorithm	Mean of four central of six total measurements and standard deviation of six measurements	Mean of four central of six total measurements and standard deviation of six measurements	N/A
Contact Tip	Light weight, disposable, single use, plastic probe with tip radius of 0.9 mm	Light weight, disposable, single use, plastic probe with tip radius of 0.9 mm	Prism as applanation surface
Anesthesia required	No	No	Yes
Contact tip sterilization	Sterilized, disposable, single use	Sterilized, disposable, single use	Prisms need to be disinfected after each patient
Power supply	2 x CR123 batteries	4 x AA batteries	Non-electrical, manually adjusted spring
Calibration	No calibration required	No calibration required	Maintenance calibration required once a month
Weight	5.29 oz (150 g)	5.47 oz without batteries (155 g)	1.1 lb (0.5 kg)
Dimensions	4.22′′ x 3.15′′ x 1.18′′ (110 mm x 80 mm x 30 mm)	1.26′′ × 3.15′′ × 9.06′′ (32 mm × 80 mm × 230 mm)	9.8′′ × 4.5′′ × 3.5′′ (250 mm × 115 mm × 89 mm)

BRIEF SUMMARY OF NONCLINICAL AND CLINICAL TESTS AND RESULTS

The following performance data are provided in support of the substantial equivalence determination:

- Risk management: The hardware and software hazards associated with the HOME system were identified and recorded in the Risk Analysis document according to ISO14971. All risks have been reduced to safe levels.

- Safety testing demonstrate the conformance to the standards and the substantial equivalence of the Icare Home Tonometer to the predicate device for electrical safety (IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007), electromagnetic compatibility (IEC 60601-1-2: 2014 Ed. 4.0) and light safety (IEC 60825-1:2001, IEC 62471:2006, EN 15004-2:2007). Additionally, testing demonstrated that the Icare Home Tonometer meets the U.S. requirements for electrical safety specified in ANSI/AAMI ES60601-1:2005.
- The Level of Concern for the Icare HOME unit is considered "moderate" based on FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Software verification and validation testing was provided commensurate with this level of concern.
- Biocompatibility testing of the Icare HOME Probe was performed in conformance with the applicable elements of ISO 10993 standard. Testing criteria were established for the Icare HOME Probe as an ocular surface contact device with transient contact duration (< 24 hours). The finished product, Icare Tonometer Probe (TP02), was evaluated to meet the particular requirements for cytotoxicity, ocular irritation, and sensitization. This testing was conducted by a qualified contract laboratory in accordance with the provisions of 21 CFR 58, Good Laboratory Practice for Nonclinical Laboratory Studies.

  The forehead and cheek support were tested for biocompatibility in accordance with ISO 10993 for the TA02 Icare ONE Tonometer. The construction of the forehead and cheek support for that product is identical to that utilized for the TA022 Icare HOME Tonometer and the results are applicable. Primary skin irritation, sensitization by guinea pig maximization, and cytotoxicity were performed by Ethox International in accordance with the applicable ISO standards and in compliance with the provisions of 21 CRF 58, Good Laboratory Practices for Nonclinical Laboratory Studies.
- Sterilization is performed by gamma irradiation and has been validated to a sterility assurance level in accordance with ISO 11137-1 and ISO 11137-2.
- Transportation tests in accordance with industry standards and packaging validation in accordance with ISO 11607-1 have been performed to ensure the package remains intact and is protective of the product throughout the 3-year shelf-life of the product.
- For determination of the 3-year shelf life, aging was performed in real-time, on finished Icare tonometer probes packaged and sterilized under routine production conditions, and aged under typical office or home storage conditions. Testing was performed at the end of the three-year aging period to ensure packaging and product integrity.

<u>Bench Performance Testing</u>

Bench testing was performed to characterize the bias and precision of the intraocular pressure (IOP) measurements from the test tonometer (Icare HOME) device and the bias and precision of the IOP measurements from a predicate tonometer (the FDA cleared Icare TA01i tonometer) over a wide range of IOP values in a manometer-controlled model. Data was collected according to ANSI Z80.10-2009 "Ophthalmic Instruments – Tonometers" (in accordance with FDA´s extent of recognition) with the following results:

1. The differences between the Icare HOME tonometer (three units) and manometer values at each pressure were less than +/- 3 mmHg. This level of accuracy is acceptable for the intended use of the HOME tonometer.
2. The standard deviations and coefficients of variation for each Icare Home tonometer are consistently low (0-8%) across the measurement range, demonstrating good precision of the Icare Home Tonometer for the measurement of pressure.
3. For the actual pressure levels of 10, 20, and 30 mmHg, the within-level measurement differences were at most 1 mmHg (= maximum – minimum), and at least 50% of the within-level measurements are the same (i.e. IQR = 0). For these pressure levels, the within-unit mean, overall mean, and average of means are close to the actual pressure level, which demonstrates excellent accuracy of the HOME measurement to the actual pressure level. For the actual levels of 40 and 50 mmHg, some of the HOME measurement differences were more than 1 mmHg compared to the actual pressure level, but these differences are relatively small compared to the actual pressure level. The within-level measurement differences at the higher-pressure levels are all within 3 mmHg, and at least 50% of measurement differences are within 1 mmHg for the level of 40 mmHg and within 2 mmHg for the level of 50 mmHg.
4. The within-unit SD, the overall SD, and the "average" SD of HOME measurements are all <0.52 mmHg; the corresponding CV values are all <5.5%. These SD and CV values show that the HOME tonometer provides IOP measurements with very high precision when the actual pressure levels are within 10 to 30 mmHg.
5. There was slightly more bias and imprecision at the very extremes of the measuring range; Differences between Icare HOME and actual pressure were observed to be within 1 mmHg in the pressure range 10-30 mmHg. At the very extremes of the measuring range, the differences were observed to be slightly larger (i.e. 2 mmHg at the 5 mmHg level and 2-3 mmHg at the 40 and 50 mmHg levels). Similarly, the precision of the device was observed to be better within the pressure range 10-50 mmHg (i.e. CV of 0.0% - 5.5%) as compared to the 5 mmHg pressure level (i.e. CV of 8.1%).
6. The performance of the HOME device was consistent across the three units and there was little variation in measurements due to operator.

In summary, the accuracy was found suitable for the home-use tonometer. Additionally, repeatability in both single and series modes of operation was established using three HOME tonometers and two operators. There was very little difference attributed to either inter-operator or inter-instrument variability.

Human factors testing

Human factors engineering (HFE) work on the design and product labeling included a series of HFE analyses, design refinement activities, formative usability tests, and culminated in simulated and actual-use validation (i.e., summative) usability tests. The Actual-Use HFE Validation Test described below demonstrated the Icare HOME tonometer is reasonably safe and effective from a human factors standpoint for use by the intended user population in the intended use

environments.

Actual-Use HFE Validation Test: An actual-use HFE validation test was conducted in the U.S. with 18 patients to supplement the findings of the simulated-use study. The procedures involved participant training/certification, scenario based testing, a 1-week home use training decay, followed by re-testing and recertification. The inclusion and exclusion criteria were as follows:

Inclusion criteria

- *Glaucoma patients that have confirmed optic nerve damage with visual field loss consistent with glaucomatous optic neuropathy, OR*
- *Glaucoma-suspect patients being followed for elevated IOP, for risk factors for developing glaucoma, or for possible optic nerve damage.*

Exclusion criteria

- *Age < 40 years*
- *Uncorrected Near Visual Acuity (UCNVA) of 20/200 or worse (binocular) in both eyes*
- *Only one functional eye*
- *Poor or eccentric fixation in one or both eyes*
- *High corneal astigmatism >3D in both eyes based on their current refractive prescription if available. Those without a prescription will undergo auto-refraction to obtain Keratometry readings.*
- *Disabling arthritis or limited motor coordination that might limit self-handling of the HOME tonometer*
- *Lack of comprehension or willingness to use the HOME tonometer as instructed*
- *Corneal scarring in both eyes*
- *History of prior incisional glaucoma surgery or corneal surgery, including corneal laser surgery in both eyes*
- *Microphthalmos in both eyes*
- *Buphthalmos in both eyes*
- *Contact lens use in both eyes*
- *Symptoms of Dry Eye Syndrome and signs of dry eye on examination of cornea in both eyes*
- *Known history of difficulty in obtaining GAT IOP measurements or any factors that might contribute to inaccurate GAT IOP measurements (e.g. lid squeezing or tremor)*
- *Nystagmus*
- *Keratoconus in both eyes*
- *Any other corneal or conjunctival pathology or infection in both eyes*
- *Central corneal thickness greater than 0.60 mm or less than 0.50 mm in both eyes*
- *Cataract Extraction within the last two months in both eyes*
- *Experience using or interacting with the HOME tonometer during a previous usability or clinical trial*
- *Any affiliation with Icare and its employees*
- *Any occupation as a healthcare professional or research and development employee at a medical device manufacturer*

The use scenarios were administered over the course of three phases as follows:

- Phase 1 – Training/Certification and Initial Testing: Each participant took part in a 30-minute device training/certification session delivered by a qualified HCP trainer (ophthalmologist, optometrist, or optometric technician). After a two-hour training decay period, the participants were asked to perform IOP measurement scenarios in each eye.
- Phase 2 – Independent Home-use Period: Each participant was directed to use the Icare HOME tonometer to measure his/ her IOP three to six times per day during the home-use period over the course of one week, and to complete a daily journal of their experiences.
- Phase 3 – Follow-up Testing and Certification: Each participant returned with the completed journal for a second, 90-minute test session. First, participants performed the HFE use scenario (self- measure the IOP in both eyes using the Icare HOME tonometer independently). Next, an eye care professional administered re-certification which included self-measurement with the Icare HOME tonometer. Finally, a subjective assessment was administered to determine root causes(s) associated with any events and participant comments.

Demographics (glaucoma status, gender, age, education level): Eighteen patients with the following characteristics participated in this Actual-Use HFE Validation Test:

- 6 glaucoma patients and 12 glaucoma-suspect patients
- Gender: 8 females and 10 males
- Age:
    - 40-49 years of age: 10 participants
    - 50-59 years of age: 5 participants
    - 60-69 years of age: 1 participants
    - 70-80 years of age: 2 participants
- Education level:
    - Completed high school or a portion thereof: 11 participants
    - College Degree: 6 participants
    - Advanced Degree: 1 participant

Findings of Phases 1 and 3: Overall, there were no safety critical observations and no adverse events reported throughout the test or during the home use period. More specifically, all 17 (100%) participants successfully completed all scenarios without committing any use errors, close calls or operational difficulties associated with critical severity outcomes. Further, none of these participants required moderator assistance to complete the scenarios.

A total of eight participants were observed performing nine non-safety critical behaviors. Of these nine instances, six occurred during Phase 1 while three occurred during Phase 3. This pattern of observations demonstrates that the one-week home-use period seemingly improved participant performance. These observations tended to occur more frequently during Scenario steps 4 (Turn knobs to adjust forehead and cheek support positioning) and 6 (Press Measure button to achieve of 6 measurements).

The non-safety critical observations along with the associated mitigation (where necessary) were as follows:

- Touched probe with finger prior to use (n=1). Labeling was revised to include the customary recommendation provided by manufacturers of contact lenses to wash and dry their hands with soap and a clean towel prior to handling the probe.
- Did not fully adjust forehead support (n=1)
- Inadvertently measured right eye instead of the left eye (n=1). There is no hazard in this event, as the device automatically detects and logs which eye is being measured.
- Used a different forehead/cheek supports setting in response to errors (n=1)
- Almost forgot to adjust forehead/cheek supports and recovered (n=2)
- Pattern of difficulty obtaining measurement (n=3)

Phase 1 Certification: At the conclusion of each training/certification session, the eye care professional assessed if the participant successfully completed the training and passed certification using the criteria specified in the protocol and device labeling (i.e. certification procedure is required for real world use of the Icare HOME Tonometer).

Out of 18 participants, one participant did not pass certification during Phase 1 and was excluded from the study due to not meeting the training/certification requirements. This is consistent with the findings of the clinical performance testing performed by Icare in which 10.7% of subjects were unable to demonstrate proficiency with the Icare Home tonometer after initial training and failed to meet these same certification criteria.

Phase 3 Certification: The HCP trainer followed the same certification criteria from Phase 1 to re-certify each participant. One participant did not pass re-certification during Phase 3 because the Icare HOME tonometer readings did not sufficiently agree with the GAT measurement.

Phase 2 (home use period): The primary purpose of the home use period was to serve as a one-week training decay.

The Icare HOME tonometer is intended for home use to monitor IOP multiple times per day (3-6 times per day specified in the product labeling). The data confirmed the practicality of patients being able to acquire a measurement a minimum of 3 times per day (only 1.8% of subject-days logged < 3 measurements) with most subjects choosing to use the device 3 times per day. 10.3% of subject-days logged 6 measurements, which is the recommended maximum number of measurements per day. With no adverse events reported during the home use period, the safety of measurements acquired 6 times per day was confirmed.

The mean attempts per successful measurement during the home-use period (1.5 per measurement) was remarkably similar to the mean attempts per successful measurement during the clinical performance testing performed under simulated home-use conditions (1.4 per measurement).

The proportion of measurements for which only one attempt was required (75.9%) was the same as the proportion observed during the clinical performance testing performed by Icare under simulated home-use conditions (75.9%).

Home-use journal entries recorded during Phase 2 were discussed with the participants during the exit interview to determine if there were any unanticipated use problems. The journal

entries did not reveal any unanticipated hazards or new use problems with only the following issues being noted by participants along with the associated mitigation (where necessary):

- Multiple attempts required in response to Service Light error (7 participants)
- Multiple attempts required due to probe not being centered (5 participants)
- Multiple attempts required due to eye blinking during probe movement (3 participants)
- Touching probe during troubleshooting due to participant's familiarity with handling contact lenses (participant reported that touching the probe with clean hands is not a concern to him) (1 participant)
    - Labeling was revised to include the customary recommendation provided by manufacturers of contact lenses to wash and dry their hands with soap and a clean towel prior to handling the probe.
- Eyes felt dry during device use (1 participant)
- Used a different forehead/cheek support setting in response to errors (1 participant)
- Dropped probe due to small size – properly discarded (1 participant)
- Multiple successful measures due to lack of confidence (1 participant)

Clinical Performance Testing

A prospective, observational, multi-center clinical trial was conducted to assess the safety of the Icare HOME tonometer and to determine the measurement agreement between self-measured IOP with the Icare HOME tonometer and clinic-measured IOP by Goldmann applanation tonometry (GAT) and by the Icare TA01i tonometer, as well as repeatability (variability between measurements taken by the same operator and the same device) of the Icare HOME tonometer compared to that of the other two methods. Performance goals for agreement as found in ANSI Z80.10-2009 were used. 460 participants age 40 or older were enrolled across five US sites and 385 eyes of 385 participants found to be eligible. Data from 376 eyes were included in the effectiveness analyses. All participants must have had a pre-existing diagnosis of glaucoma or 'glaucoma suspect.' Participants were trained by study staff as part of the certification procedure on how to use the Icare HOME tonometer. After a 10-minute break, the participants were asked to make three self-measurements without any direct supervision or interaction. Study staff then acquired three measurements on the Icare TA01i tonometer, then an eye care professional took two GAT measurements (a third if the first two were not within 2 mm Hg of each other). Other testing procedures included auto-refraction, auto-keratometry, discomfort assessment using the Visual Analog Scale (VAS) questionnaire, assessment of fluorescein staining of the cornea and Oxford scheme grading of any corneal epithelial defects, and corneal pachymetry.

Inclusion criteria were as follows:

Patients with pre-existing diagnosis of "glaucoma" or "glaucoma suspect" in the study eye(s):

- *Glaucoma suspects will include patients being followed for elevated IOP, for risk factors for developing glaucoma, or for possible optic nerve damage.*
- *Glaucoma patients will have confirmed optic nerve damage with visual field loss consistent with glaucomatous optic neuropathy.*

Exclusion criteria were as follows:

- *Age < 40 years • Uncorrected Near Visual Acuity (UCNVA) of 20/200 (binocular)*
- *Subjects with only one functional eye*
- *Subjects having poor or eccentric fixation in the study eye*
- *Hearing impaired to the extent that the individual cannot hear and converse with others without an assistive aid and/or sign language*
- *High corneal astigmatism >3D in the study eye(s) based on their current refractive prescription if available. Those without a prescription will undergo auto-refraction to obtain Keratometry readings.*
- *Disabling arthritis or limited motor coordination limiting self-handling of the Icare Home tonometer*
- *Lack of comprehension or willingness to use the tonometer as instructed*
- *Corneal scarring*
- *History of prior incisional glaucoma surgery or corneal surgery, including corneal laser surgery in the study eye*
- *Microphthalmos*
- *Buphthalmos*
- *Contact Lens Use*
- *Symptoms of Dry Eye Syndrome and signs of dry eye on examination of cornea*
- *Known history of difficulty in obtaining Goldmann IOP measurements or any factors that might contribute to inaccurate Goldmann IOP measurements (e.g. lid squeezing or tremor)*
- *Nystagmus*
- *Keratoconus*
- *Any other corneal or conjunctival pathology or infection*
- *Central corneal thickness greater than 0.60 mm or less than 0.50 mm in the study eye*
- *Inability to demonstrate proficiency with Icare Home tonometer after training and failure to complete certification procedures described in the attachment to this protocol*
- *Cataract Extraction within last 2 months in study eye*

10.7% (49/460) of subjects failed to complete the certification procedures described in the protocol for the following reasons:

- Three Home readings differed by > 7mmHg (0.7%)
- The first Home reading and the GAT measurement differed by > 5mmHg (6.3%)
- Subject requested to stop (0.7%)
- Subject unable to use the device (3.0%).

Table 2 provides demographics of the completed eligible subjects and distribution of intraocular pressures.

TABLE 2. DEMOGRAPHICS OF THE COMPLETED ELIGIBLE SUBJECTS AND DISTRIBUTION OF IOP

Demographics		Overall
Age	N	383
	Mean (SD)	66.1 (12.6)
	Min, Max	35, 95
Gender	Male	171 (44.6%)
	Female	212 (55.4%)
Race	Asian Indian	2 (0.5%)
	Black/ African American	70 (18.3%)
	Black/African American, American Indian or	1 (0.3%)
	Black/African American,	1 (0.3%)
	Chinese	15 (3.9%)
	Chinese, Korean	1 (0.3%)
	Filipino	8 (2.1%)
	Filipino, Japanese	1 (0.3%)
	Japanese	157 (41.0%)
	Korean	9 (2.3%)
	Native	1 (0.3%)
	Other Asian	5 (1.3%)
	Vietnamese	1 (0.3%)
	White	108 (28.2%)
	Refused	3 (0.8%)
Ethnicity	Not Spanish/Hispanic / Latino	355 (92.7%)
	Mexican, Mexican Am., Chicano	16 (4.2%)
	Puerto Rican	2 (0.5%)
	Other Spanish/Hispanic / Latino	10 (2.6%)
Handedness	Right	355 (92.7%)
	Left	23 (6.0%)
	Ambidextrous	5 (1.3%)
Study Eye	OD (Right)	206 (53.8%)
	OS (Left)	177 (46.2%)
IOP Group	≤ 16 mmHg	146 (38.1%)
	> 16 to <23 mmHg	169 (44.1%)
	≥ 23 mmHg	68 (17.8%)

% = Count ÷ N × 100.

In Table 3, the descriptive statistics for the IOP measurements from the Icare Home, GAT, and TA01i are provided.

TABLE 3. DESCRIPTIVE STATISTICS OF IOP MEASUREMENTS (EFFECTIVENESS ANALYSIS COHORT)

Device	Statistics	≤ 16 mmHg	> 16 to <23 mmHg	≥ 23 mmHg	Overall
Home First Measurement	N	143	167	66	376
	Mean	**12.44**	**18.26**	**26.18**	**17.44**
	SD	3.18	2.91	5.52	6.01
	Median	12.00	18.00	25.00	17.00
	IQR	5.00	4.00	5.00	6.50
	Minimum	3.00	11.00	20.00	3.00
	Maximum	20.00	27.00	51.00	51.00
GAT Mean/Median Measurement	N	143	167	66	376
	Mean	12.86	18.99	26.41	17.96
	SD	2.17	1.78	4.86	5.50
	Median	13.00	18.50	24.50	17.50
	IQR	3.00	3.00	3.00	7.00
	Minimum	5.00	16.50	23.00	5.00
	Maximum	16.00	22.50	53.00	53.00
GAT First Measurement	N	143	167	66	376
	Mean	**13.29**	**18.31**	**24.71**	**17.53**
	SD	2.60	2.84	5.10	5.18
	Median	13.00	18.00	23.00	17.00
	IQR	3.00	5.00	5.00	7.00
	Minimum	5.00	11.00	18.00	5.00
	Maximum	20.00	25.00	50.00	50.00
TA01i Mean/Median Measurement	N	143	167	66	376
	Mean	12.93	19.14	26.53	18.07
	SD	2.36	1.77	4.92	5.56
	Median	13.00	19.00	25.00	18.00
	IQR	4.00	3.00	3.00	7.00
	Minimum	6.00	16.00	22.00	6.00
	Maximum	20.00	23.00	53.00	53.00
TA01i First Measurement	N	143	167	66	376
	Mean	**13.27**	**18.11**	**24.80**	**17.44**
	SD	2.64	2.97	5.58	5.32
	Median	13.00	17.00	23.00	17.00
	IQR	3.00	4.00	5.00	7.00
	Minimum	6.00	12.00	17.00	6.00
	Maximum	20.00	25.00	53.00	53.00

Mean/Median: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Table 4 provides the limits of agreement between the HOME tonometer and the two reference tonometers. The mean difference and standard deviation (Icare HOME - GAT) were -0.53 mmHg and 2.43 mmHg, respectively. All ANSI performance goals were met as less than 5% of measurements fell outside ± 5 mmHg at each pressure range and less than 1% fell outside ± 7.5 mmHg at each pressure range.

TABLE 4. LIMITS OF AGREEMENT BETWEEN HOME AND REFERENCE (EFFECTIVENESS ANALYSIS COHORT)

Group	N	Home Mean (SD)	Reference Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference	Outside ± 5 mmHg n (%)	Outside ± 7.5 mmHg n (%)
Reference: GAT (Mean/Median Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	12.86 (2.17)	-0.42 (2.54)	-0.84, -0.00	-5.50, 4.65	4 (2.8%)	1 (0.7%)
> 16 to <23 mmHg	167	18.26 (2.91)	18.99 (1.78)	-0.73 (2.36)	-1.09, -0.37	-5.45, 3.99	7 (4.2%)	0 (0.0%)
≥ 23 mmHg	66	26.18 (5.52)	26.41 (4.86)	-0.23 (2.39)	-0.81, 0.36	-5.00, 4.55	1 (1.5%)	0 (0.0%)
Overall	**376**	**17.44 (6.01)**	**17.96 (5.50)**	**-0.53 (2.43)**	**-0.77, -0.28**	**-5.39, 4.34**	**12 (3.2%)**	**1 (0.3%)**
Reference: GAT (First Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	12.93 (2.36)	-0.49 (2.55)	-0.91, -0.07	-5.59, 4.61		
> 16 to <23 mmHg	167	18.26 (2.91)	19.14 (1.77)	-0.87 (2.46)	-1.25, -0.50	-5.80, 4.06		
≥ 23 mmHg	66	26.18 (5.52)	26.53 (4.92)	-0.35 (2.41)	-0.94, 0.25	-5.18, 4.48		
Overall	376	17.44 (6.01)	18.07 (5.56)	-0.64 (2.49)	-0.89, -0.38	-5.62, 4.35		
Reference: TA01i (Mean/Median Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	13.29 (2.60)	-0.85 (2.60)	-1.28, -0.42	-6.06, 4.35		
> 16 to <23 mmHg	167	18.26 (2.91)	18.31 (2.84)	-0.05 (2.56)	-0.44, 0.34	-5.16, 5.07		
≥ 23 mmHg	66	26.18 (5.52)	24.71 (5.10)	1.47 (3.07)	0.72, 2.22	-4.67, 7.61		
Overall	376	17.44 (6.01)	17.53 (5.18)	-0.09 (2.78)	-0.37, 0.19	-5.65, 5.48		
Reference: TA01i (First Measurement)								
≤ 16 mmHg	143	12.44 (3.18)	13.27 (2.64)	-0.83 (2.64)	-1.26, -0.39	-6.10, 4.45		
> 16 to <23 mmHg	167	18.26 (2.91)	18.11 (2.97)	0.16 (2.65)	-0.25, 0.56	-5.14, 5.45		
≥ 23 mmHg	66	26.18 (5.52)	24.80 (5.58)	1.38 (3.30)	0.57, 2.19	-5.22, 7.98		
Overall	376	17.44 (6.01)	17.44 (5.32)	-0.00 (2.87)	-0.29, 0.29	-5.74, 5.73		

N is the number of eyes with measurements from both devices.
Difference = HOME - Reference.
95% confidence interval (CI) for mean difference is based on t-distribution. 95% limits of agreement (LOA) = mean difference ± 2 × difference SD.
% = n ÷ N × 100.
The first HOME IOP measurement of each study eye was used in the analysis.
Mean/Median: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Table 5 below provide correlations between the IOP measurements and pachymetry measurements.

TABLE 5. LIMITS OF AGREEMENT BETWEEN HOME AND GAT BY CENTRAL CORNEAL THICKNESS (CCT) EFFECTIVENESS ANALYSIS COHORT

CCT Group	N	Home Mean (SD)	GAT Mean (SD)	Difference Mean (SD)	95% CI for Mean Difference	95% LOA for Mean Difference	Outside ± 5 mmHg n (%)	Outside ± 7.5 mmHg n (%)
500-520	94	17.43 (5.70)	18.01 (5.28)	-0.59 (2.46)	-1.09, -0.08	-5.50, 4.33	3 (3.2%)	0 (0.0%)
521-540	100	16.52 (6.50)	16.87 (5.99)	-0.35 (2.03)	-0.75, 0.06	-4.40, 3.71	1 (1.0%)	0 (0.0%)
541-560	95	17.98 (6.55)	18.28 (5.93)	-0.30 (2.59)	-0.83, 0.23	-5.47, 4.87	3 (3.2%)	0 (0.0%)
561-580	57	17.70 (5.53)	18.61 (4.72)	-0.91 (2.86)	-1.67, -0.15	-6.64, 4.81	4 (7.0%)	1 (1.8%)
581-600	30	18.33 (4.03)	19.25 (3.87)	-0.92 (2.22)	-1.75, -0.09	-5.36, 3.53	1 (3.3%)	0 (0.0%)
Overall	**376**	**17.44 (6.01)**	**17.96 (5.50)**	**-0.53 (2.43)**	**-0.77, -0.28**	**-5.39, 4.34**	**12 (3.2%)**	**1 (0.3%)**

N is the number of eyes with measurements from both devices.
Difference = HOME - Reference.
95% confidence interval (CI) for mean difference is based on t-distribution.
95% limits of agreement (LOA) = mean difference ± 2 × difference SD.
% = n ÷ N × 100.
The first HOME IOP measurement of each study eye was used in the analysis.
The Mean/Median of GAT was used in the analysis: the median was used if the eye had three measurements. Otherwise, the mean was used if the eye had two measurements.

Table 6 provides the repeatability analyses for all measurements in the effectiveness analysis cohort. The HOME repeatability (CV%) was comparable for the low and medium IOP range (~10% for each bin) and smaller for the high IOP range (~7.5%).

TABLE 6. REPEATABILITY ALL MEASUREMENTS OF EFFECTIVENESS ANALYSIS COHORT

Group	Number of Subjects	Mean	Repeatability		
			SD	Limit	CV%
HOME					
≤ 16 mmHg	143	12.7	1.6	3.6	10.07
> 16 to <23 mmHg	167	18.4	3.7	5.4	10.44
≥ 23 mmHg	66	26.7	4.1	5.7	7.61
Overall	376	17.7	3.0	4.8	9.76
GAT					
≤ 16 mmHg	143	12.9	0.8	2.5	6.97
> 16 to <23 mmHg	167	19.0	0.7	2.4	4.46
≥ 23 mmHg	66	26.4	2.6	4.5	6.07
Overall	376	18.0	0.9	2.6	5.18
TA01i					
≤ 16 mmHg	143	13.3	0.9	2.6	7.08
> 16 to <23 mmHg	167	18.3	1.4	3.3	6.37
≥ 23 mmHg	66	24.9	2.1	4.1	5.87
Overall	376	17.6	1.3	3.2	6.53

All statistics are estimated from a random-effect model with study eye and error as the random effect.
Mean = Intercept of the ANOVA model
Repeatability SD = Square root of the residual variance.
Repeatability limit = 2.8 x Repeatability SD.
Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Safety: No adverse events (including corneal abrasions) were recorded in this study population of 383 eyes. Anterior corneal epithelial grading was performed at baseline and after each attempt to measure IOP using the Oxford Scheme (a scale from 0-5) illustrated in the study protocol. It should be noted that these findings represent a "worst case scenario" as during the study visit subjects underwent more HOME measurements in a short period of time compared to what would be experienced by patients in real world use of the device. Nonetheless, under these study conditions, only 5% of eyes experienced an increase in staining after certification compared to baseline and only one eye (0.3%) experienced an increase of two grades or more which is generally considered a clinically significant change due to variability in the slit lamp grading scales. After the series of three HOME measurements (bringing the total of HOME measurements to four plus the one GAT certification measurement), the number of eyes experiencing an increase in staining increased to 11.3%; however, only five (1.3%) eyes experienced a clinically significant increase in staining. Furthermore, it should be noted that GAT induced an increase of two grades or more in two study eyes which is not unexpected. After all HOME measurements had been taken, no subject experienced an increase of three grades or more in staining compared to baseline. Before certification, after certification, and after the series of HOME validation measurements, subjects were asked to rate eye discomfort by placing a vertical mark on the VAS horizontal line to indicate the level of eye discomfort. 0% corresponds to "no discomfort" and 100% corresponds to "maximal discomfort". There was essentially no change in discomfort following the certification procedures (which consisted of three HOME measurements and one GAT measurement) and the series of three HOME validation measurements. The median change from baseline was zero and the maximum increase was only 23 units on the 100 point VAS scale.

The results of the study demonstrated that Icare HOME is safe and performed as intended when used according to its indications for use and in accordance with its labeling.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Icare HOME tonometer to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

CONCLUSIONS

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