K063873

5. 510(k) Summary

MAY 23 2007

Summary prepared: December 21, 2006

Submitted by

Company name:	Tiolat Oy
Company address:	Nuijamiestentie 5 B 00400 Helsinki Finland
Contact person:	Kari Serjamaa, CEO
Phone number:	+358 9 8775 1150
Fax number:	+358 9 728 6670

US Agent to respond to FDA requests:

Contact person:	Nelson Tobin
Company name:	Diagnostic Instrument Group
Company address:	8404 Sunstate Street Tampa, FL 33634
Phone number:	(813) 926-3447
Fax number:	(813) 926-7954

Proposed Device

Manufacturer:	Tiolat Oy
Device name:	iCare Tonometer
Model name:	TA01i
Classification name:	86HKX
Regulation number:	886.1930
Device class:	Class II

5.1 Intended Use

The iCare Tonometer TA01i is intended to be used for the measurement of intraocular pressure of the human eye.

5.2 Device Description

The iCare Tonometer TA01i is a portable, handheld, battery operated tonometer, which measures intraocular pressure (IOP). To measure IOP, a very light (26.5 mg) and a slow moving (0.25-0.30 m/s) probe makes momentary contact with the cornea of the eye. The device measures the speed of the probe during the time probe is in contact with cornea. Resulting IOP is displayed on a liquid crystal display (LCD). The force used for the measurement which is directed onto the eye is extremely small, because of the low weight and slow speed of the probe.

5.3 Predicate Devices

The iCare Tonometer TA01i is judged to be substantially equivalent in safety, effectiveness and intended use to the following legally marketed devices:

Manufacturer:	HAAG-STREIT
Device name:	APPLANATION TONOMETER AT 900
Classification name:	86HKY
Regulation number:	886.1930
Device class:	Class II
510(k) number:	K981432

Manufacturer:	MEDTRONIC
Device name:	MEDTRONIC TONO-PEN XL
Classification name:	86HKY
Regulation number:	886.1930
Device class:	Class II
510(k) number:	K053430

Manufacturer:	SMT SWISS MICROTECHNOLOGY AG
Model name:	PASCAL DYNAMIC CONTOUR TONOMETER
Classification name:	86HKY
Regulation number:	886.1930
Device class:	Class II
510(k) number:	K032967

Manufacturer:	RYAZAN STATE INSTRUMENT-MAKING ENTERPRISE
Model name:	Tonometer TGDc-01 "PRA"
Classification name:	86HKX
Regulation number:	886.1930
Device class:	Class II
510(k) number:	K021937

5.4 Substantial Equivalence Comparison

In Tables 5.1, 5.2, 5.3 and 5.4 the iCare Tonometer TA01i is compared to predicate devices to show the equivalence. The comparison of intended use and technological features of iCare Tonometer TA01i indicate that the device is substantially equivalent to legally marketed predicate devices.

Table 5.1. iCare Tonometer TA01i vs. Haag-Streit Applanation Tonometer AT-900 (Goldmann type)

	iCare Tonometer TA01i	Haag-Streit AT-900
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Slit lamp mounted manual dial
Measurement technique	Rebound	Applanation
Calibration	No maintenance calibration required	
Contact tip	Lightweight, disposable, single use, plastic probe (26.5mg)	Prism as applanation surface
Contact tip sterilization	Sterilized, disposable, single use	Prisms need to be disinfected after each patient
Patient interface	Probe briefly touches the eye	Held on patient's eye while dial is adjusted
Force caused to eye by measurement	8–16 mN	10–50 mN (1g = 1/100N =10mN)
Display	4 digit LCD (2 digit reading)	Scribed dial
Range of measurement	7–50 mmHg (display range 1–99 mmHg)	0–80
Versatility	Patient can be measured in any position, but the tonometer must be oriented horizontally	Patient can be measured in sitting position
Anesthesia required	No	Yes
Weight	5.47 oz. without batteries (155 g)	1.10 lb (0.5 kg)
Dimensions	1.26″ × 3.15″ × 9.06″ (32 mm × 80 mm × 230 mm)	(250 mm × 115 mm × 89 mm)
Power source	4 × 1.5 Volt AA batteries	–

Table 5.2. iCare Tonometer TA01i vs. Tono-Pen XL

	iCare Tonometer TA01i	Tono-Pen XL
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Same
Measurement technique	Rebound	Applanation
Calibration	No maintenance calibration required	Same
Contact tip	Light weight, disposable, single use, plastic probe with tip radius of 0.9 mm	1.0 mm transducer tip, applanation surface approximately 3 mm
Contact tip sterilization	Sterilized, disposable, single use	Sanitized natural latex tip covers
Patient interface	Probe briefly touches eye	Briefly touched against eye
Force caused to eye by measurement	8–16 mN	Depending on user, uncontrolled
Display	4 digit LCD (2 digit reading)	Same
Range of measurement	7–50 mmHg (display range 1–99 mmHg)	5–80 mmHg
Versatility	Patient can be measured in any position, but the tonometer must be oriented horizontally	Patient can be measured in any position
Anesthesia required	No	Same
Weight	5.47 oz. without batteries (155 g)	2.25 oz. (64 g)
Dimensions	1.26″ × 3.15″ × 9.06″ (32 mm × 80 mm × 230 mm)	7 1/4″ × 1″ × 7/8″ (184.2 mm × 25.4 mm × 22.2 mm)
Power source	4 × 1.5 Volt AA batteries	2 × OCU-CEL™ XL batteries

Table 5.3. iCare Tonometer TA01i vs. Pascal dynamic contour tonometer (DCT)

	iCare Tonometer TA01i	Pascal DCT
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Slit lamp mounted microprocessor based
Measurement technique	Rebound	Dynamic contour
Calibration	No maintenance calibration required	Self calibrating
Contact tip	Light weight, disposable, single use, plastic probe with tip radius of 0.9 mm	Sensor tip 7 mm, pressure sensor 1.2 mm
Contact tip sterilization	Sterilized, disposable, single use	Sterile, single use disposable tip cover
Patient interface	Probe briefly touches the eye	
Force caused to eye by measurement	8–16 mN	10 mN (constant 1 gram)
Display	4 digit LCD (2 digit reading)	LCD display
Range of measurement	7–50 mmHg (display range 1–99 mmHg)	5–200 mmHg
Versatility	Patient can be measured in any position, but the tonometer must be oriented horizontally	Same
Anesthesia required	No	Yes
Weight	5.47 oz. without batteries (155 g)	7.41 oz. (210 g)
Dimensions	1.26″ × 3.15″ × 9.06″ (32 mm × 80 mm × 230 mm)	6.69″ × 3.46″ × 1.57″ (170 mm × 88 mm × 40 mm)
Power source	4 × 1.5 Volt AA batteries	3 V battery pack

Table 5.4. iCare Tonometer TA01i vs. Tonometer TGDc-01 "PRA"

	iCare Tonometer TA01i	Tonometer TGDc-01 "PRA"
Indication	Intraocular pressure (IOP) measurement	Same
Design	Hand-held microprocessor based	Hand-held microprocessor based
Measurement technique	Rebound	Same, but measurement to upper eyelid
Calibration	No maintenance calibration required	No maintenance calibration required
Contact tip	Light weight, disposable, single use, plastic probe with tip radius of 0.9 mm	–
Contact tip sterilization	Sterilized, disposable, single use	–
Patient interface	Probe briefly touches the eye	Touches the upper eyelid
Display	4 digit LCD (2 digit reading)	4 digit LCD (2 digit reading)
Range of measurement	7–50 mmHg (display range 1–99 mmHg)	0–60
Versatility	Patient can be measured in any position, but the tonometer must be oriented horizontally	Patient can be measured in any position, but the tonometer must be oriented downwards
Anesthesia required	No	No
Weight	5.47 oz. without batteries (155 g)	2.79 oz. (79g)
Dimensions	1.26'' × 3.15'' × 9.06'' (32 mm × 80 mm × 230 mm)	6.83'' × 1.00'' × 0.77'' (173.5mm × 25.5mm × 19.5mm)
Power source	4 × 1.5 Volt AA batteries	4 × 1.5 Volt batteries (CR2032)

5.5 Summary of Non-Clinical and Clinical Testing

The performance of iCare Tonometer TA01i has been evaluated in bench testing. The units under test met the acceptance criteria of the operating range, accuracy and repeatability.

In clinical evaluation, the performance of iCare Tonometer TA01i was compared to predicate devices, including Goldmann type tonometer.

Based on the results of non-clinical and clinical testing, the performance of iCare Tonometer TA01i is judged to be substantially equivalent to predicate devices.

The patient contacting probe is considered biocompatible. The appropriate tests for biocompatibility were performed according to "ISO 10993-1:2003, Biological evaluation of medical devices – Part 1 Evaluation and Testing".

The electromagnetic compatibility and electrical safety of the iCare Tonometer TA01i was tested and found to conform to the requirements of IEC 60601-1 and IEC 60601-1-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tiolat Oy
c/o Mr. Nelson Tobin
Diagnostic Instrument Group
8404 Sunstate Street
Tampa, Fl 33634

MAY 23 2007

Re: K063873
Trade/Device Name: iCare Tonometer TA01i
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer
Regulatory Class: Class II
Product Code: HKX
Dated: May 9, 2007
Received: May 10, 2007

Dear Mr. Tobin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): not assigned yet

Device Name: iCare Tonometer TA01i

Indications for Use:

The iCare Tonometer TA01i is intended to be used for the measurement of intraocular pressure of the human eye.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K063873