



October 23, 2023

Huvitz Co., Ltd.
% Dave Kim
President
Mtech Group
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K232143
Trade/Device Name: Applanation Tonometer HT-5000
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: September 21, 2023
Received: September 21, 2023

Dear Dave Kim:

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.

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,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232143

Device Name

The Applanation Tonometer HT-5000

Indications for Use (Describe)

The Applanation Tonometer HT-5000 is a manual device intended to measure an intraocular pressure by applanation to aid in the diagnosis of glaucoma.

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.

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5. 510(k) Summary

The Summary of 510(k) safety and effectiveness is being submitted to comply with 21 CFR Part 807.92.

General Information

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Device Information:

- Trade Name: The Applanation Tonometer
- Proprietary Name: HT-5000
- Device Classification Name: Tonometer, Manual
- Regulation Number: 21 C.F.R. 886.1930,
- Classification: Class II
- Product Code: HKY
- Review Panel: Ophthalmic

Predicate Device Information:

- 510(k) Number: K133234
- Trade Name: Digital Keeler Applanation Tonometer (D-KAT)
- Proprietary Name: R-type KAT
- Device Classification Name: Tonometer, Manual
- Regulation Number: 21 C.F.R. 886.1930
- Product Code: HKY
- Review Panel: Ophthalmic

Description:

The Applanation Tonometer HT-5000 is an active medical device, powered by AAA batteries. The device can be used in conjunction with slit lamp microscopes which are commercially available. Components of the tonometer contains applanation tonometer main body, weight bars, connection arms and measuring prisms.

Indication for Use:

The Applanation Tonometer HT-5000 is a manual device intended to measure an intraocular pressure by applanation to aid in the diagnosis of glaucoma.

Intended Use:

The Applanation Tonometer HT-5000 is indicated for measurement of intraocular pressure (IOP). Intraocular pressure (IOP) is a very important physiological parameter and has always been an indispensable part of the diagnosis and treatment of ophthalmology, especially for glaucoma.

The operation principle is based on Goldmann applanation method, which is considered as the gold standard for measuring intraocular pressure. The applanation tonometer plays an important role in the diagnosis and treatment of ophthalmic diseases.

Method of Operation:

Applanation Tonometer is an appliance which intends to measure intraocular pressure based on Goldmann method, also known as Goldmann Applanation Tonometer (GAT). The intraocular pressure, measured by applanation tonometer, is computed from the force required to flatten a constant area of the cornea.

Huvitz Applanation Tonometer HT-5000 is designed in accordance with the Goldmann method which measures intraocular pressure to maintain a uniform applanation of the surface of the eye.

A disinfected or sterile disposable measuring prism is mounted on the Tonometer head at the end of the measurement arm and placed against the cornea after the cornea has been anaesthetized. By moving the slit lamp, the measuring prism comes into contact with the center of the cornea over the pupillary area. The examiner uses a cobalt blue filter to view the semi-circle then adjust the measurement drum on applanation tonometer to apply force to the tonometer head till the inner edges of the semicircle appears in the view where the prism applanation surface becomes $\varnothing = 3.06$ mm (area = 7.354 mm²). The value is presented on the digital display.

Calibration

During factory calibration procedure, known pressures covering the measurement range are applied to the measurement arm using a calibration arm using calibration bars verified using the calibration procedure described in the Tonometer Standard ISO 8612:2009. Calibration provides a relationship between pressure applied to the measurement arm and the position of the rotating measuring drum. Lineal interpolation is used between the calibration points.

Substantial Equivalence

Huvitz Applanation Tonometer HT-5000 is considered to be substantially equivalent to the predicate device Digital Keeler Applanation Tonometer R-type KAT(K133234). HT-5000 has the same intended use, indications for use, technical features and principles of operation as R-type KAT which has been previously cleared by FDA.

Features	Predicate Device Digital Keeler Applanation Tonometer R-type D-KAT K133234	Subject Device The Applanation Tonometer HT-5000	Notes
Type	Manual Contact Tonometer	Manual Contact Tonometer	Same
Indication for Use	The Keeler Applanation Tonometer is indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	The Applanation Tonometer HT-5000 is a manual device intended to measure an intraocular pressure by applanation to aid in the diagnosis of glaucoma.	Same
Units of measure	mmHg-millimeter of mercury	mmHg-millimeter of mercury	Same
Design	Slit lamp mounted manual dial	Slit lamp mounted manual dial	Same
Measurement Range	5-65 mmHg	3-75 mmHg	HT-5000 has a wider measurement range than Keeler's. However, the difference doesn't affect safety, effectiveness or the intended use.
Display	Numerical Display-Direct read-out of IOP in mmHg from display	Numerical Display-Direct read-out of IOP in mmHg from display	Same
Measurement Deviation	0.49mN or 1.5% of measurement value whichever is the greater	0.49mN or 1.5% of measurement value whichever is the greater	Same
Power Requirement	Single AA battery to power digital display	4-AAA battery to power digital display	As voltage is high, the power efficiency increases. However, the difference doesn't affect

			safety and effectiveness.
Software	Contains software	Contains software	Same
Measurement Method	Goldmann method- the measuring of pressure to maintain a uniform applanation of the surface of the eye	Goldmann method- the measuring of pressure to maintain a uniform applanation of the surface of the eye	Same
Calibration	Maintenance and calibration required Factory Set Calibration arm assembly is supplied with each device to check calibration	Maintenance and calibration required Factory Set Calibration arm assembly is supplied with each device to check calibration	Same
Biocompatibility	All materials are tested for biocompatibility	All materials are tested for biocompatibility	Same
Cleaning and Disinfection Instruction for Tonometer Prisms	Disinfectants, concentration and time of immersion– Pantasept- 3% aqueous solution for 10 minutes, Hydrogen Peroxide 3% aqueous solution for 10 minutes Sodium Hypochlorite- 10% aqueous solution for 10 minutes	Disinfectants, concentration and time of immersion– Hydrogen Peroxide 3% aqueous solution for 10 minutes Sodium Hypochlorite- 500 ppm aqueous solution for 10 minutes	Cleaning and disinfection instruction for tonometer prisms are the same. The difference in concentration of disinfectant such as sodium hypochlorite doesn't significantly affect effectiveness and safety.
Tonometer Prisms recommended shelf-life	Recommend that the prism is not used when it becomes more than two years of age	Recommend using of two years after first use in normal conditions or recommends that the tonometer prism be replaced after 600 cycles of disinfection with dilute bleach in 10 minutes	The recommended shelf-life of tonometer prisms is slightly different from each other. Effectiveness and safety was verified in the reliability test.
Sterilization of Tonometer Prisms	Non-Sterile	Non-Sterile	Same

Electrical Safety and Electromagnetic Capability (EMC)

All necessary safety testing was conducted on the subject device and demonstrated that HT-5000 is substantially equivalent to the predicate device in terms of safety and effectiveness. The safety testing included the followings:

1. Electrical and Mechanical Safety Testing (according to IEC 60601-1, Edition 3.2)
2. Electromagnetic Compatibility (according to IEC 60601-1-2, Edition 4.1)
3. ISO 15004-1:2020 Ophthalmic instruments -- Fundamental requirements and test methods -Part 1: General requirements applicable to all ophthalmic instruments.

Disinfection Validation

Disinfection/cleaning procedure was applied according to a FDA guidance 'Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling'

A disinfection and cleaning validation was conducted to evaluate performance and safety after a tonometer prism is exposed to a cleaner or to a disinfectant and during defined period.

Proposed disinfection/cleaning procedure and disinfectants doesn't affect damage of mechanical characteristics, degradation of performance characteristics and degradation of biological characteristics during defined period.

Biocompatibility

The biocompatibility evaluation for patient contact material (Measuring prism) of Huvitz Applanation Tonometer was conducted in accordance with ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021 as recognized by FDA. The patient-contact part of HT-5000 is the front surface of measuring prisms.

Contact time: $t \leq \text{Max. 30 second}$

Patient's contact part: Patient's cornea.

The Applanation tonometer prism of testing included the following tests:

- Vitro-Cytotoxicity
- Skin Sensitization
- Ocular Irritation

Based upon results obtained from studies and in line with ISO10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021, Applanation Tonometer prism supplied by Huvitz Co., Ltd is considered as non-cytotoxic, non-sensitizer and doesn't cause ocular irritant.

Performance Testing

Bench testing was conducted to verify the measuring force in accordance with ANSI Z80.10-2014, Ophthalmic Instruments Tonometer.

Bench testing was conducted by two different experimenters to measure six different weight values for 10 times in three devices. In addition, one investigator measured each weight values in 3 devices and predicate devices to compare accuracy. The results indicated that HT-5000 provided reliable and

repeatable IOP measurements within provided IOP range and, HT-5000 met the specified tolerance as the predictive device.

All necessary verification testing was conducted on the subject device under ANSI Z80.10-2014, Ophthalmic Instruments Tonometer and demonstrated that HT-5000 is substantially equivalent to the predicate device in terms of performance and effectiveness

Software

The software used in HT-5000 has been verified against design requirements, as required by IEC 62304:2015 Medical device software - Software life cycle processes.

Conclusion:

HT-5000 has the similar intended use and technological features as the predicate device. Any differences between HT-5000 and the predicate device do not raise any questions regarding safety and effectiveness.

All bench testing and analysis demonstrated that the subject device is substantially equivalent with its predicate device and that the device is safe and effective as intended.