Medimaging Integrated Solution Inc
Luu Hsu
Regulatory Affairs
3F, No. 24-2, Industry E. Rd. IV, Hsinchu Science Park
Hsinchu, Taiwan 30077

Re: K223739
Trade/Device Name: VS Tabletop Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: September 28, 2023
Received: September 29, 2023

Dear Luu Hsu:

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
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)*
K223739

Device Name
VS Tabletop Tonometer

Indications for Use *(Describe)*
The VS Tabletop Tonometer is a digital tonometer intended to measure 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# Medimaging Integrated Solution Inc.

## 510(k) Summary

**Prepared** November 07, 2023

**Submitter** Medimaging Integrated Solution Inc. (MiiS)

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**Device:**

**Trade/Device Name:** VS Tabletop Tonometer
**Model name:** IOP 100
**Regulation Number:** 21 CFR 886.1930
**Regulation Name:** Tonometer and accessories
**Regulatory Class:** Class II
**Product Code:** HKX

**Predicate Device:**

**Primary predicate device:**
K181260
**Trade/Device Name:** MiiS Horus Scope DPT 100
**Regulation Number:** 21 CFR 886.1930
**Regulation Name:** Tonometer and accessories
**Regulatory Class:** Class II
**Product Code:** HKX

**Secondary Predicate Device**
K180820
**Trade/Device Name:** Tono Vue Non-Contact Tonometer
**Regulation Number:** 21 CFR 886.1930
**Regulation Name:** Tonometer and accessories
**Regulatory Class:** Class II
**Product Code:** HKX

**Description of Device:**

The VS Tabletop Tonometer (VS TT) is a non-contact, table-top tonometer used to measure intraocular pressure of the eye. The tonometer is based on the previously cleared MiiS tonometer, the Horus Scope DPT 100 (K181260). The core technology element of the VS TT is the air puff module, which is equivalent to the air puff module used in the DPT 100 predicate device. The measurement method and measurement algorithm of the VS TT and DPT 100 devices are the same.

The main technological difference between the VS TT and the predicate DPT 100 is that the VS TT features an auto-alignment system that automatically brings the air puff module within a positional range with respect to the patient's cornea such that the air puff module is able to perform the IOP measurement. The auto-alignment system of the subject device performs the same pre-positioning adjustments that are performed manually by clinical staff with the DPT 100. Hence, the consequence of these design modifications is that a clinical staff member is not required to perform an intermediary, non-critical step in measurement acquisition.

The VS TT device is intended to be used by patients in doctor's office with the assistance from eye care professional. Patients are first trained on how to use the device.

The VS TT measures IOP in the range of 7-55 mmHg. It contains a graphical user interface on a color LCD touchscreen display where the IOP results are displayed.

The device is powered by a rechargeable lithium-ion battery. It can either be used alone (i.e. not plugged in) or connected to a power adapter.

**Indications for Use:**

The VS Tabletop Tonometer is a digital tonometer intended to measure intraocular pressure of the human eye.

**Comparison of Technological Characteristics with Predicate Devices**

| Characteristic | VS Tabletop Tonometer (Model IOP 100)<br><br>Subject Device | Horus Scope (Model DPT-100) K181260<br><br>Primary Predicate Device | TonoVue Non-Contact Tonometer K180820<br><br>Secondary Predicate | Comparison to Predicate Devices |
|---|---|---|---|---|
| **General information** | | | | |
| Manufacturer | Medimaging Integrated Solution Inc. (MiiS) | Medimaging Integrated Solution Inc. (MiiS) | Crystalvue Medical Corporation | - |

| Characteristic | VS Tabletop Tonometer (Model IOP 100)<br><br>Subject Device | Horus Scope (Model DPT-100) K181260<br><br>Primary Predicate Device | TonoVue Non-Contact Tonometer K180820<br><br>Secondary Predicate | Comparison to Predicate Devices |
|---|---|---|---|---|
| Device Classification | Class II | Class II | Class II | Same |
| Classification Product Code | HKX | HKX | HKX | Same |
| Regulation Number | 21 CFR 886.1930 | 21 CFR 886.1930 | 21 CFR 886.1930 | Same |
| Intended use | A digital tonometer intended to measure intraocular pressure of the human eye. | A digital tonometer intended to measure intraocular pressure of the human eye. | A digital tonometer intended to measure intraocular pressure of the human eye. | Same |
| Using environment | Health care environment | Health care environment | Health care environment | Same |
| **Specification** | | | | |
| Contact area | Non-contact | Non-contact | Non-contact | Same |
| Hand Held or Table Top | Table Top | Hand held | Table Top | Same as Secondary Predicate. |
| Working distance | 12 mm | 12 mm | 11 mm | Same as Primary Predicate |
| Measurement Type | Air-puff | Air-puff | Air-puff | Same |
| IOP Measurement range | 7-55 mmHg | 7-55 mmHg | 1-60 mmHg | Same as Primary Predicate. Within the range of the Secondary Predicate. |
| IOP Measurement Accuracy | within 5 mmHg | within 5 mmHg | unknown | Same as Primary Predicate |

| Characteristic | VS Tabletop Tonometer (Model IOP 100)<br><br>Subject Device | Horus Scope (Model DPT-100) K181260<br><br>Primary Predicate Device | TonoVue Non-Contact Tonometer K180820<br><br>Secondary Predicate | Comparison to Predicate Devices |
|---|---|---|---|---|
| **Principles of Operation** | | | | |
| Operator | Patient self-measurement in clinic with the assistance from eye care professional | Measured by eye care professional | Measured by eye care professional | Different. See discussion below. |
| Head stabilization | Patient rests their brow and cheek bone against the eyepiece | Patient rests their head in a chin rest | Patient rests their head in a chin rest | Different. See discussion below. |
| Measurement of relative position between the eye and the air puff module | Glint Detection System | Glint Detection System | Unknown | Same as Primary Predicate |
| Positioning the air puff module | Auto-alignment | Manual alignment | Auto-alignment | Similar to Secondary Predicate in that both devices automatically position the air puff module.<br><br>Different from the primary predicate. See discussion below. |
| Obtaining the IOP measurement | Automatic. Once air puff module detects that the center of the eye is in the right position, pneumatic and applanation systems are automatically activated | Automatic. Once air puff module detects that the center of the eye is in the right position, pneumatic and applanation systems are automatically activated | Automatic. Once air puff module detects that the center of the eye is in the right position, pneumatic and applanation systems are automatically activated | Same |

| Characteristic | VS Tabletop Tonometer (Model IOP 100)<br><br>Subject Device | Horus Scope (Model DPT-100) K181260<br><br>Primary Predicate Device | TonoVue Non-Contact Tonometer K180820<br><br>Secondary Predicate | Comparison to Predicate Devices |
|---|---|---|---|---|
| **Interface and Power Specification** | | | | |
| User interface | LCD touch panel | LCD touch panel | LCD touch panel | Same |
| Communication interface | No interface | Mini USB | USB-A, RS-232 | Different. Since this difference pertains to data storage and device interface, it does not affect safety or effectiveness. |
| Power source | Lithium-ion rechargeable battery and/or AC power | Lithium-ion rechargeable battery | AC power | Equivalent |
| Input voltage | 100~240 VAC, 50/60 Hz | 100~240 VAC, 50/60 Hz | 100~240 VAC, 50/60 Hz | Same |
| **Dimension and appearance** | | | | |
| Weight | 4 kg | 1.06 kg | 17 kg | Differences are based on ergonomic design differences required for self-measurement. These differences do not affect safety or Effectiveness. |
| Dimension | 319 mm x 166 mm x 260 mm | 111 mm x 105 mm x 193 mm | 500 mm x 282 mm x 500 mm | |
| Product appearance |  |  |  | |

**Discussion of Substantial Equivalence**

- The VS TT has the same intended use and use environment as the predicate DPT 100 (K181260) and TonoVue (K180820) devices.
- The VS TT utilizes the same IOP measurement type (air puff) as both predicate devices, and its air puff module has an equivalent design to the primary predicate DPT 100
- The VS TT has the same measurement range as the primary predicate and its measurement range falls within the range of the second predicate.
- The VS TT has an equivalent method for positioning its air puff module as the Tono Vue (Secondary Predicate).
- The VS TT is different from the predicate devices in that the VS TT is operated primarily by the patient in clinic (with eye care professional assistance), whereas the predicate devices are operated by an eye care professional. However, since all 3 devices share the same air-puff technology, and the air puff module is only triggered once the patient's eye is positioned within the eye box of the air puff module in all 3 devices, this difference in who operates the devices does not affect the accuracy of the IOP measurement. Therefore, this difference does not affect the safety or effectiveness of the device.
- Other differences (i.e. head stabilization method, interfaces, dimensions and appearance) are minor and do not affect device safety or effectiveness.

**Performance and Safety data**

Based on the risk analysis and design control requirements, a program of design verification and validation testing was performed on the VS TT that includes the following:

- Electromagnetic compatibility (IEC 60601-1-2: 2020-09) and electrical safety (IEC 60601-1:2005/AI:2012/A2:2020)
- Software verification and validation (IEC 62304: 2015-06)
- Biocompatibility testing (ISO 10993-1: 2018-08; ISO 10993-5: 2009-06; ISO 10993-10:2010-08)
- Fundamental requirements for ophthalmic instruments (ISO 15004-1: 2020-5)
- Optical radiation hazard testing and classification (ANSI Z80.36-2021)
- Performance testing
- Environment testing (ISTA-3A: 2018)
- Battery testing (IEC 62133-2:2017-02)
- Usability assessment (IEC 60601-1-6: 2013-10 and IEC 62366: 2015-02)

Since the air puff modules used in the predicate DPT 100 device and the subject VS TT device have the same technology and same performance specifications, the IOP

measurements made with the VS TT and the DPT 100 are equivalent. Clinical validation performed on the VS TT demonstrated the addition of the auto-alignment feature is successful in aligning to a human eye within a duration of 4.5 - 20 seconds.

**Conclusion**

The comparison of the VS TT to the predicate devices, the MiiS Horus Tonometer DPT 100 K181260) and the Tono Vue Non-contact Tonometer (K180820), demonstrate that the VS TT has the same intended use as the predicate devices and that the technological differences between the VS TT and the predicate devices do not raise new questions about safety and effectiveness of the VS TT. Bench testing has been performed to show that the VS TT meets performance and safety requirements. Clinical validation shows the VS TT automatically aligns to the eye in 4.5-20 seconds. Together, this evidence demonstrates that the VS TT is substantially equivalent to the predicate devices and is safe and effective for its intended use.