June 21, 2019

Medimaging Integrated Solution Inc. (MiiS)
Chih-Lu Hsu
COO
1F, No.7, R&D Rd. II
Hsinchu Science Park
Hsinchu, 30076 Cn

Re: 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
Dated: June 14, 2019
Received: June 17, 2019

Dear Chih-Lu 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 (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 located 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.

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

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 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,

Bradley Cunningham
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)*
K181260

Device Name
MiiS Horus Scope DPT 100

Indications for Use *(Describe)*
MiiS Horus Scope DPT 100 is a digital portable tonometer used to measure intraocular pressure of eyeball.

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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Medimaging Integrated Solution Inc.

510(k) Summary

Prepared:	April 26, 2018
Submitter/Owner's Name/ Address	Medimaging Integrated Solution Inc. (MiiS) 1F, No.7, R&D Rd. II, Hsinchu Science Park, Hsinchu, Taiwan 30076 (R.O.C.)
Contact Person: Telephone: Fax: Email Address:	Mr. Luu Hsu +886-3-5798860 Ext: 1700 +886-3-5798011 luu@miis.com.tw

Device Identification:

Trade/Device Name MiiS Horus Scope DPT 100
Regulation Number: 21 CFR 886.1930
Regulation Name: Non-Contact Tonometer
Regulatory Class: Class II
Product Code: HKX

Predicate Device:

K013259
Trade/Device Name: Reichert PT100 Portable (Tonometer)
Regulation Number: 21 CFR 886.1930
Regulation Name: Non-Contact Tonometer
Regulatory Class: Class II
Product Code: HKX

K871335
Trade/Device Name: TOPCON COMPUTERIZED TONOMETER CT-80
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer, AC-Powered
Regulatory Class: Class II
Product Code: HKX

Description of Device:

MiiS Horus Scope DPT 100 is a Li-ion battery-powered device. The Li-ion battery is re-chargeable. It is a digital portable tonometer used to measure intraocular pressure of eyeball.

The device uses a white LED for illumination and capture image. The device has been tested according to the ISO 15004-2 (first edition, 2/15/2007) and been classified as Group I device.

The device has a CMOS sensor. The sensor accomplishes a task of capturing light and converting it into electrical signals.

The device store images to a SD card and have connectivity towards PC. The device uses an USB 2.0 interface to transfer data or picture to PC when connected.

The operation method of the device is described step by step in the attachment A1 “User manual”. There is a graphical user interface color TFT display and keypad that is used for making adjustments before and during measure intraocular pressure of eyeball. Its’ measure rang is 7-55 mmHg.

Indications for Use:

MiiS Horus Scope DPT 100 is a digital portable tonometer used to measure intraocular pressure of eyeball.

Substantial Equivalence Summary

Key technological summaries and differences between the device and the predicate devices:

NO.	Items	Device	Predicate Device 1	Predicate Device 2	Same/Difference Interpretation
1	Submitter	Medimaging Integrated Solution Inc.	Reichert, Ltd.	Topcon	Difference
	Product Name	Digital Portable Tonometer	Portable Non-Contact Tonometer	Computerized Tonometer	Equivalent
	Model Name	MiiS Horus Scope DPT 100	PT100	CT-80	-
	K Number	K181260	K013259	K871335	-
	Product code and Classification	21 CFR 886.1930, HKX Class II	21 CFR 886.1930, HKX Class II	21 CFR 886.1930, HKX Class II	Same
2	Intended use	MiiS Horus Scope DPT 100 is a digital portable tonometer used to measure intraocular pressure of eyeball.	The PT100 is a hand held non contact tonometer intended to measure the intraocular pressure of the eye.	CT-80 is an exact, non-contact intraocular pressure measurement that can be done by air ejection.	Same
3	Weight	1060g	1260g (Measurement head)	18kg	Difference
4	Dimension	111mm x 105mm x 193mm	254mm x 127mm x 205mm	272(W)×505(D)×430~458(H)mm	Difference
5	Contact area	non-contact	non-contact	non-contact	Same
6	Working distance	12mm	12mm	11mm	Equivalent
7	Measurement range	7-55mmHg	0-60mmHg	0-60mmHg	Equivalent
8	Measurement scale	mmHg	mmHg	mmHg	Same
9	Inspection Window	3.5" Capacitive LCD touch panel	Eyepiece	Monitor screen	Difference
10	Interface	Mini USB	USB	RS232C	Equivalent
11	Power source	Lithium-ion rechargeable battery	Lithium-ion rechargeable battery	Power cable connect to the wall power	Equivalent
12	Input voltage	100~240 VAC, 50/60 Hz	100~240 VAC, 50/60 Hz	AC 100, 120, 220, 230 and 240V; 50/60Hz	Equivalent

13	Product appearance				Difference

Substantial Equivalence Discussion

Similarities:

- MiiS Horus scope DPT 100 and predicate device, Reichert PT100 Portable (Tonometer) have the same intended use. Both devices have same specifications, such as contact area, working distance, power source and input voltage. DPT 100 has similar specifications to Reichert PT100 Portable (Tonometer), such as the measurement range, measurement scale, weight, dimension and connection interface.

- MiiS Horus scope DPT 100 and predicate device, Topcon CT-80 Computerized Tonometer have the same intended use. DPT 100 has similar specifications to Topcon CT-80 Computerized Tonometer, such as the working distance, measurement range, measurement scale and input voltage.

Differences:

- The major differences are inspection window. MiiS Horus scope DPT 100 has 3.5" Capacitive LCD touch panel. But, Reichert, Ltd. PT100 use eyepiece to observe.

- The major differences between MiiS Horus scope DPT 100 and Topcon CT-80 Computerized Tonometer are weight, dimension, inspection window, interface, power source and product appearance.

- These variants don’t impact on device safety and effectiveness.

Non-clinical and Clinical Tests

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

1. EMC and electrical safety testing were conducted on the DPT 100. The device complies with IEC/EN 60601-1-2:2014/2015 for EMC and IEC/EN 60601-1:2005/2006+A1:2012/ 2013 for Safety.
2. Software verification and validation testing was done according to IEC 62304.
3. Risk management: DPT 100 was evaluated according to ISO 14971:2007 and EN ISO 14971:2012. All risks have been reduced to safe levels thus there is no conflict between risk and benefit.
4. Tests for ophthalmic products: DPT 100 was tested in accordance with ISO 15004-2:2007 standards and was found to meet all requirements of the standards. For optical hazards was classified to Group 1.

5. Biocompatibility: The contact part to patient is the holder of chin rest CR100. The holder material was tested in accordance with ISO10993-5:2009 and ISO10993-10:2010 standards.
6. Tests for tonometer:

   The performance of MiiS DPT 100 has been evaluated in bench test. The units under test met the acceptance criteria of the operating range, accuracy, repeatability and reproducibility with a manometer-controlled model. We also do Clinical Performance Test, and found a Goldmann applanation tonometry (GAT) Keeler Digital Applanation Tonometer (D-KAT) (K133234) to do the human eye Clinical performance test compared to MiiS DPT 100. Data was collected according to ISO 8612:2009 and ANSI Z80.10-2014 “Ophthalmic Instruments – Tonometers” (in accordance with FDA´s extent of recognition) with the following results.

Conclusion

Substantial equivalence comparison and bench performance tests support the conclusion of substantial equivalence of MiiS Horus scope DPT 100 to the predicate devices.