January 14, 2020

Medimaging Integrated Solution Inc. (MiiS)
Yi-Ying Chen
Regulatory Affairs
3F, No.24-2, Industry E. Rd. IV, Hsinchu Science Park
Hsinchu, 30077 Cn

Re: K193188
Trade/Device Name: MiiS Horus Eye Anterior Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO, HKI
Dated: November 18, 2019
Received: November 18, 2019

Dear Yi-Ying Chen:

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,

for Tieuvi Nguyen, Ph.D.
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)*
K193188

Device Name
MiiS Horus Eye Anterior Camera

Indications for Use *(Describe)*
MiiS Horus Eye Anterior Camera is a digital hand-held slit lamp system indicated for non- invasive illumination, magnification, visualization and to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.

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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510(k) Summary

Prepared: January 9, 2020

Submitter/Owner's Name/ Address Medimaging Integrated Solution Inc. (MiiS)
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yimmy.chen@miis.com.tw

Device Identification:

Trade/Device Name: MiiS Horus Eye Anterior Camera
Common Name: Digital Eye Anterior Camera, Digital Ophthalmoscope, Slit lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO, HKI

Predicate Device:

K170470
Trade/Device Name: MiiS Horus^{+} Scope DEA 200
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO, HKI

Description of Device:

MiiS Horus Eye Anterior Camera is a digital hand-held slit lamp system indicated for non-invasive illumination, magnification, visualize and to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area. It is a Li-ion battery-powered optical device. It brings more complete medical records about the static photos as well as the dynamic videos. MiiS Horus Eye Anterior Camera has an LED light source with visible white light. The device is designed with high-resolution lens and 5M pixels CMOS Sensor, faithful rendering color of the anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area. The device can store pictures or videos in memory card, or via the USB, Wi-Fi and Bluetooth transfer pictures or videos to a computer. In addition to rendering images in the 3.5-inch full color TFT-LCD, through the HDMI output, you can connect the device to the big screen (TV, LCD screen) showing the pictures or videos.

MiiS Horus Eye Anterior Camera includes two models. The first model consists of control unit DSC 300 and lens unit DEA 200. The second model consists of control unit DSC 300P and lens unit DEA 200P. Either auto or manual focus can be used in first model while only manual focus is used in the second model.

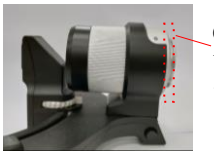
The control unit DSC 300 includes a cover glass while DSC 300P does not. The contact rim in lens unit DEA 200 is different from that in DEA 200P.

Indications for Use (IFU):

MiiS Horus Eye Anterior Camera is a digital hand-held slit lamp system indicated for non-invasive illumination, magnification, visualization and to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.

Substantial Equivalence Summary

Below is a summary table comparing the IFUs and key technological characteristics between the subject and the predicate devices.

Device	K193188		K170470
Model name	MiiS Horus Scope DSC 300 MiiS Horus^{+} Scope DEA 200	MiiS Horus Scope DSC 300P MiiS Horus Scope DEA 200P	MiiS Horus^{+} Scope DEA 200
Intended use	MiiS Horus Eye Anterior Camera is a digital hand-held slit lamp system indicated for non-invasive illumination, magnification, visualize and to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.		MiiS Horus^{+} Scope DEA 200 is a digital hand-held slit lamp system indicated for non-invasive illumination, magnification, visualization and to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.
Slit Lamp			
Slit length	10 mm Fixed		10 mm Fixed
Slit Width	≤0.2, 0.2, 0.5, 2, 5,10 mm		≤0.2, 0.2, 0.5, 2, 5,10 mm
Slit projection angle	± 45 degree (+/-5%)		± 45 degree (+/-5%)
Filter	Blue, Green		Blue, Green
Working distance	80mm (+/- 5%)		80mm (+/- 5%)
The lens unit	 Contact rim	 Contact ring would be longer 2 mm than DEA 200	 Contact rim

Digital Camera			
Focus	Auto & Manual Focus	Manual Focus	Auto & Manual Focus
Picture Resolution	2560X1920 pixels		2560X1920 pixels
Video Resolution	2560X1920 pixels		1280X960 pixels
Display	Display on the TFT-LCD or connect to and display on computer		Display on the TFT-LCD or connect to and display on
Image storage	Memory card and could be transfer to user's computer		Memory card and could be transfer to user's computer
Interface	A. USB B. HDMI C. Wi-Fi D. Bluetooth		A. USB B. AV
The control unit	 Cover glass	 **NO** cover glass	 Cover glass
Light Source			
Type	White LED		White LED
Light Intensity Adjustment	Six levels: 0B, 1B, 2B, 3B, 4B, 5B		Six levels: 0B, 1B, 2B, 3B, 4B, 5B
System			
Power Source	Lithium-ion rechargeable battery		Lithium-ion rechargeable battery
The camera system			

Substantial Equivalence Discussion

Similarities:

- MiiS Horus Eye Anterior Camera and the predicate device, MiiS Horus^{+} Scope DEA 200 (K170470), have the same intended use and same specifications in focusing capabilities, picture resolution, working distance, slit length, slit width, slit projection angle, light source, filters, image storage, display function, appearance, input voltage, power source, size and weight.

Differences:

- The primary differences between the subject and predicate devices are the electronic interfaces of the devices.
  - The subject device (K193188) can be connected to a display screen or a computer through the universal serial bus (USB), high-definition multimedia interface (HDMI), Wi-Fi, or Bluetooth while the predicate device (K170470) is through USB or audio-visual (AV) port.
  - The subject device has higher video resolution (2560x1920 pixels) than that of the predicate device (1280x960 pixels).

Nonclinical Tests

The following tests have been performed in support of the substantial equivalence determination:

- IEC 62304 for Software verification and validation testing.
- IEC/EN 60601-1:2005/2006+A1:2012/2013 for electrical safety.
- IEC/EN 60601-1-2:2014/2015 for electromagnetic compatibility.
- Bluetooth testing for compatibility and functionality.
- HDMI compliance test was conducted in compliance with HDMI 1.4b sink and source devices.
- ISO 14971:2007 and EN ISO 14971:2012 for risk management.
- ISO 15004-2:2007 for light hazards.
- ISO10993-5:2009 and ISO10993-10:2010 standards for biocompatibility. The patient contacting parts are the holder of chin rest CR100 and the forehead stopper.

Clinical Tests

No clinical studies were performed.

Optical Radiation Safety Assessment

The MiiS Horus Eye Anterior Camera was tested according to 15004-2:2007 to determine acceptable light safety limits for both the illumination and background lights. The test results demonstrate the MiiS Horus Eye Anterior Camera is in compliance with the of Group 2 instrument requirements provided by the standard.

Conclusion

Substantial equivalence comparison and bench performance tests support the conclusion of substantial equivalence of MiiS Horus Eye Anterior Camera to the predicate devices MiiS Horus^{+} Scope DEA 200 (K170470).