October 6, 2017

Medimaging Integrated Solution Inc. (miis)
% Yi-Ying Chen
Engineer
1F, No.7, R&D Rd. II
Hsinchu Science Park
Hsinchu, Taiwan 30076 (R.O.C.)

Re: K170470
Trade/Device Name: Digital Eye Anterior Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO, HKI
Dated: August 24, 2017
Received: August 29, 2017

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Bradley S. Cunningham -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170470

Device Name
MiiS Horus+ Scope DEA 200

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Medimaging Integrated Solution Inc.

K170470

510(k) Summary

Prepared:	October 1, 2017
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.)
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Device Identification:

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

Predicate Device:

1. K063640
   Trade/Device Name: Kowa SL-15 Slit Lamp
   Regulation Number: 21 CFR 886.1850
   Regulation Name: AC-powered slit lamp biomicroscope
   Regulatory Class: Class II
   Product Code: HJO

2. K120982
   Trade/Device Name: MiiS Horus Scope DEC 100
   Regulation Number: 21 CFR 886.1120
   Regulation Name: Ophthalmic Camera
   Regulatory Class: Class II
   Product Code: HKI

Description of Device:

MiiS Horus^{+} Scope DEA 200 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^{+} Scope DEA 200 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 SD memory card, or via the USB transfer pictures or videos to a computer. In addition to rendering images in the 3.5-inch full color TFT-LCD, through the AV output, you can connect the device to the big screen (TV, LCD screen) showing the pictures or videos. Below includes a summary of the technical information used in the substantial equivalence comparison. It is more efficient and suitable for many different applications, such as electronic filing.

Indications for Use:

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.

Substantial Equivalence Summary

Key technological seminaries and differences between the ICON and the predicates:

Device	K170470	K063640 Predicate Device	K120982 Predicate Device
Model name	MiiS Horus^{+} Scope DEA 200	KOWA SL-15	MiiS Horus Scope DEC 100
Intended use	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.	KOWA SL-15 is an ophthalmic device indicated for non-invasive illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and an AC-powered stand.	MiiS Horns Scope DEC 100 is a digital hand-held eye-fundus camera used to record digital photographs and video of fundus of the human eye and surrounding area.
Slit Lamp			
Slit selection	Turret-type switching	Turret-type switching	
Slit length	10 mm Fixed	12 mm Fixed	
Slit Width	≤0.2, 0.2, 0.5, 2, 5, 10 mm	0.1, 0.2, 0.8 mm and Ø 12mm spot	
Slit projection angle	± 45 degree (+/- 5%)	60 degree for Horizontal	
Filter	Blue, Green	Blue	None
Digital Camera			
Picture/Video	Built-in	Supports electronic image with the optional camera connection adapter (C-mount).	Built-in
Image sensor	CMOS	CCD	CMOS

<table>
<tr><td>Magnification</td><td>10X / 16X</td><td>10X / 16X</td><td>0.25X</td></tr>
<tr><td>Display</td><td>Display on the TFT-LCD or connect to and display on computer</td><td>Connect to and display on the camera and computer display.</td><td>Display on the TFT-LCD or connect to and display on computer</td></tr>
<tr><td>Image storage</td><td>SD card and could be transfer to user’s computer</td><td>User’s computer</td><td>SD card and could be transfer to user’s computer</td></tr>
<tr><td colspan="4">Light Source</td></tr>
<tr><td>Type</td><td>White LED</td><td>Halogen Lamp</td><td>White LED and Infrared LED</td></tr>
<tr><td>Maximum Output power</td><td>2.9V, 1.0 W</td><td>7.5V, 15 W</td><td>2.9V, 1.0 W</td></tr>
<tr><td>Light Intensity Adjustment</td><td>Six selection: 0B, 1B, 2B, 3B, 4B, 5B

From 0 mw /cm^2 to 19.12 mw/cm^2</td><td>Three selection: Full, 1/2 and 1/4</td><td>Sixteen selection:
0B, 1B, 2B, 3B, 4B, 5B, 6B, 7B, 8B, 9B, 10B, 11B, 12B, 13B, 14B, 15B
<table><tr><td></td><td>White LED</td><td>Infrared LED</td></tr><tr><td>Cornea</td><td>338.21 mw/cm^2</td><td>3.11 mw/cm^2</td></tr><tr><td>Retina</td><td>3.88 mw/cm^2</td><td>0.036 mw/cm^2</td></tr></table></td></tr>
<tr><td>External light</td><td>Background Light</td><td>None</td><td>None</td></tr>
<tr><td colspan="4">System</td></tr>
<tr><td>Power Source</td><td>Lithium-ion rechargeable battery</td><td>Lithium-ion rechargeable battery</td><td>Lithium-ion rechargeable battery</td></tr>
<tr><td>Appearance Outline Drawing</td><td> 
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  </td></tr>
</table>

Substantial Equivalence Discussion

Similarities:

- MiiS Horus^{+} scope DEA 200 and the primary predicate device, KOWA SL-15, have the same intended use. DEA 200 has similar specifications to KOWA SL-15, such as the working distance, slit length, slit width, filters, light weight and magnification function.

- Both MiiS Horus^{+} scope DEA 200 and secondary predicate device, MiiS Horus scope DEC 100 are Medimaging Integrated Solution Inc. (MiiS)'s products. They have same concept of design for image sensor, display function and image storage.

Differences:

- The Major differences are the Changes in light sources and optical system. Optical radiation hazard evaluation was performed that these changes will not affect the device safety.

Nonclinical and Clinical Tests

In this submission, the nonclinical tests were conducted, such as software (S/W) and hardware (H/W), EMC, safety and light hazard. The results of this testing indicate that the MiiS Horus^{+} scope DEA 200 is equivalent to predicate device.

No clinical studies were performed.

Optical Performance

The MiiS Horus^{+} Scope DEA 200 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 DEA 200 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^{+} Scope DEA 200 to the predicate devices (KOWA SL-15 and MiiS Horus Scope DEC 100).