Medimaging Integrated Solution Inc.

SEP 28 2012

510(k) Summary

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR 807.92.

The assigned 510(k) number is K120982

Date Prepared: February 26, 2012

Submitter and Contact Information:

FDA Establishment Registration Number: 3009197913

Manufacturer/ Address:	Medimaging Integrated Solution, Inc. (MiiS) 1F, No.7, R&D Rd. II, Hsinchu Science Park, Hsinchu, Taiwan 30076 (R.O.C.)
Contact	Name: Hsu, Chih-Lu Title: COO Telephone: +886-3-5798860 Ext: 110 Fax: +886-3-5798821 Email Address: luu@miis.com.tw
Device Name	MiiS Horus Scope DEC 100
Common Name	Digital Eye-Fundus Camera
Classification Name	Ophthalmic Camera
Classification	Class II
Regulation Number	886.1120
Product Code	HKI
Review Panel	Ophthalmic
Predicate Device	• K110986 Smartscope M5 EY3 Optomed Oy

Device Description	MiiS Horus 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. It is more efficient and suitable for many different applications, such as telemedicine and electronic filing.
Intended Use	MiiS Horus 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.
Substantial Equivalence	MiiS Horus Scope DEC 100 is substantially equivalent to the predicate device with respect to functionality, design verification, intended use and performance characteristics.
Conclusion	Based on the 510(k) summaries and the information provided herein, we conclude that the submitted device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medimaging Integrated Solution, Inc.
c/o Mr. Chih-Lu Hsu, Chief Operations Officer
1F, No. 7, R & D Rd. II
Hsinchu Science Park
Hsinchu, Taiwan 30076
R.O.C.

SEP 28 2012

Re: 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
Dated: September 12, 2012
Received: September 17, 2012

Dear Mr. 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Medimaging Integrated Solution Inc.

Indications for Use

510(K) Number (If Known): _____

Device Name: MiiS Horus Scope DEC 100

Indications for Use: MiiS Horus Scope DEC 100 is a digital hand-held eye-fundus camera used to record digital photographs and video of the fundus of the human eye and surrounding area.

Prescription Use___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Daniel Kaufman M.D.

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120982