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K123208

5. 510(k) Summary

MAR 1 9 2013

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Contact/Application Correspondent	Izumi Maruo MIC International 4-1-17 Hongo, Bunkyo-ku, Tokyo, 113-0033, Japan TEL: 81-3-3818-8577 FAX: 81-3-3818-8573 maruo@mici.co.jp
Date Prepared:	October 10, 2012
Trade Name:	Digital Retinal Camera CR-2 Plus AF
Common Name:	Ophthalmic camera
Classification Name:	Ophthalmic camera. (21 CFR 886.1120, Product code HKI)
Regulation Class	II
Predicate Device:	K111612 Canon Digital Retinal Camera CR-2 Plus
Device Description:	The *Digital Retinal Camera CR-2 Plus AF* is used for taking digital images of a human retina without a mydriatic. Canon EOS Digital Camera is mounted to the *CR-2 Plus AF*. Images can be viewed immediately, and procedures of imaging are more efficient with many different applications such as telemedicine and electronic filing. The *CR-2 Plus AF* is equipped with autofocus/automatic shooting/automatic switching function from anterior segment image to fundus image.
Statement of Intended Use:	The *CR-2 Plus AF* is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The *CR-2 Plus AF* has the following photography modes: color, red free, cobalt digital and fundus autofluorecence (FAF).

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Modification from predicate device	The *CR-2 Plus AF* is modified from the CR-2 Plus by adding following functions; • Autofocus of the fundus image • Automatic shooting of the fundus image • Automatic switching from anterior segment image to fundus image In addition, the "diopter compensation knob" is removed since diopter compensation is performed using the focus ring instead of the diopter compensation knob in the *CR-2 Plus AF*.
Statement of Substantial Equivalence	The *CR-2 Plus AF* has the same intended use and fundamental technological characteristics as the CR-2 Plus. However, the *CR-2 Plus AF* has some different technological characteristics compared to the CR-2 Plus as described above. In order to evaluate safety and effectiveness of the *CR-2 Plus AF,* non-clinical tests were performed. In conclusion, result of the testing demonstrated that the *CR-2 Plus AF* does not raise any new safety and effectiveness concerns compared to the CR-2 Plus.
Summary of Non-Clinical/Test Data:	Non-clinical tests were conducted to evaluate safety and effectiveness of the *CR-2 Plus AF* as follows. Performance testing, Software Validation, Electrical safety, and Electromagnetic Compatibility testing have been performed. The unit complies with the US Performance Standard for ophthalmic equipment. The *CR-2 Plus AF* met all requirements of the standards.
Conclusion:	*Canon, Inc. – Medical Equipment Group* concluded that the *CR-2 Plus AF* is substantially equivalent to the predicate device listed above. This conclusion is based on the identical intended use and fundamental technological characteristics, and the similarities in the functional design. Although the *CR-2 Plus AF* has some different technological characteristics from the predicate, the non-clinical testing results indicated that the *CR-2 Plus AF* met all requirements of recognized or voluntary standard. Based on the test results, the *CR-2 Plus AF* does not raise any new safety and effectiveness concerns compared to the CR-2 Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 19, 2013

Canon Inc. Medical Equipment Group
% Izumi Maruo
MIC International Corp.
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0033

Re: K123208
Trade/Device Name: Digital Retina Camera CR-2 Plus AF
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: March 5, 2013
Received: March 7, 2013

Dear Izumi Maruo:

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,

Kesia Y. Alexander -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

Indications for Use

510(k) Number (if known): K123208

Device Name: Digital Retinal Camera CR-2 Plus AF

Indications For Use:

The Digital Retinal Camera CR-2 Plus AF is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The CR-2 Plus AF has the following photography modes: color, red free, cobalt digital and fundus autofluorescence (FAF).

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)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K123208_____