K101628

Kowa Company. Ltd.

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510(k) Summary

JAN 2 6 2011

Submitter information:

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Contact: Satohiko Takanashi, PE

Date summary prepared: June 9, 2010

Device identification:

Device trade name: KOWA nonmyd WX
Classification name: Camera, Ophthalmic, AC-powered
Product code: HKI, NFJ

Identification of predicate devices:

Kowa Company believes that this device is substantially equivalent to:
KOWA nonmyd 7 manufactured by Kowa, 510(k)# K053026,
Nidek 3-DX/3-DXF Stereo Disc/Fundus Cameras manufactured by Nidek, 510(k)# K973533.

Device description:

The KOWA nonmyd WX is a retinal camera without mydriatic. Plane retinal image capturing function, that is normal image capturing, is equipped and furthermore, stereo image capturing function is done. The stereo images are able to take simultaneously in shingle shot, as these images are captured without image/parallax shifts.

The KOWA nonmyd WX consists of a device body and external digital SLR camera, Single-Lens Reflex camera.

The KOWA nonmed WX uses Xenon flash lamp as an image capturing light and Infrared LED lamp as an observation light.

The KOWA nonmyd WX can be sued even in case which pupil has not been completely dilated in plane image capture mode, if it is more than 3.7mm in diameter.

The KOWA nonmyd WX is equipped with a USB port to be able to transfer images to a computer.

The KOWA nonmyd WX is designed to be able to link up to a filling system (KOWA portable VK-2), which can manage the digital images.

Intended use:
KOWA nonmyd WX is intended for use with plane and stereo retinal image capturing without mydriatic. The retinal image can be stored to an image filing device through serial interface.

Technical characteristics:
Electrical safety
To guarantee Electrical safety, IEC60601-1 test was performed. The nonmyd WX met all requirements of the standard.

Electromagnetic compatibility
To guarantee Electromagnetic compatibility, IEC60601-1-2 test was performed. The nonmyd WX met all requirements of the standard.

Optical safety
To guarantee Optical safety, evaluation based on ISO15004-2 was performed. The nonmyd WX met all requirements of Group 1 instrument in the standard.

Software evaluation
To make sure Software validity of the nonmyd WX embedded software and filing software, evaluation based on FDA guidance, Guidance for the content of premarket submissions for software contained in medical devices, 2005, was performed.
The levels of concern of these software items are minor.
The validation of these software items is performed as a part of system function test. All functions are tested and confirmed good working to required items.

Biocompatibility
To guarantee biocompatibility, biocompatibility assessment was performed. All materials were used the same of the other legally marked devices in US.

Risk Management
The nonmyd WX was evaluated in accordance with ISO14971: 2007, and met to all requirements of standard. The risk management of the device was deemed satisfactory. Remaining risks will be noted in the user manual, so users will be able to avoid them.

Conclusion

KOWA nonmyd WX is equipped with the fundamental technology to the predicate device for retinal image capturing and also deliver the equivalent level of safety. Therefore, it is concluded that there is no difference in the basic functions and safety between KOWA nonmyd WX and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Kowa Co, Ltd.
c/o Mr. Satohiko Takanashi
4-14, Nihonbashi-honcho 3-chome
Chuo-ku Tokyo, 103-8433
Japan

JAN 26 2011

Re: K101628
Trade/Device Name: Kowa nonmyd WX
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: II
Product Code: HKI
Dated: October 13, 2010
Received: October 14, 2010

Dear Mr. Takanashi:

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,

for Kesia Alexander

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

Indications for Use

510(k) Number (if know): K101628

Device Name: KOWA nonmyd WX

Indications for Use:

KOWA nonmyd WX is intended for use with plane and stereo retinal image capturing without mydriatic. The retinal image can be stored to an image filing device through serial interface.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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