Kowa Company, Ltd.

ELECTRONICS & OPTICS DIVISION
4-14, NIHONBASHIHONCHO 3-CHOME,
CHUO-KU, TOKYO 103-8433 JAPAN

510 k #: K093387

Applicant	Kowa Company, Ltd 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan
Contact	Akihiro Fujita
Date Summary Prepared	November 14, 2008
Device Trade Name	KOWA nonmyd α-DIII
Classification name	CAMERA, OPTHALMIC, AC-POWERED SYSTEM, IMAGE MANAGEMENT, OPHTALMIC
Product Code	HKI NFJ

JAN 16 2009

Intended use
KOWA nonmyd α-DIII, fundus camera, is intended for use with retinal image capturing without mydriatic The retinal image can be stored to an image filing drive through serial interface

Comparison
The KOWA nonmyd α-DIII(Type 1) was chosen as a substantially equivalent device

The KOWA nonmyd α-DIII is similar to the predicate device in that it is equipped with a highly sensitive CCD camera, does not require film for photography, and allows for immediate viewing of the image after image is captured

The modifications that are made are

- Change the power supply
- Change the CCD camera to the same resolution, 8 3M pixels, and the same sensitivity camera by the other manufacturer
- Add the montage function in the associated software
- Add the advanced search function in the associated software

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Table A: Predicate device			
Predicate Device	**Manufacturer**	**510(k) No.**	**Date Cleared**
KOWA nonmyd α-DIII (Type 1)	Kowa Company, Ltd	K082767	Oct 21,2008

Conclusion

The KOWA nonmyd α-DIII is equipped with the same fundamental technology as the predicate device and maintains the same level of safety performance Therefore it has been concluded that there are no significant differences in the fundamental function or safety between KOWA nonmyd α-DIII and the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kowa Company, LTD
c/o Akihiro Fujita, General Manager
Electronics & Optics Division
4-14, Nihonbashihoncho 3-Chome,
Chou-Ku, Tokyo
Japan 103-8433

JAN 16 2009

Re K083387
Trade/Device Name KOWA nonmyd α-DIII (Type 2)
Regulation Number 21 CFR 886 1120
Regulation Name Ophthalmic Camara
Regulatory Class Class II
Product Code HKI, NFJ
Dated December 16, 2008
Received December 18, 2008

Dear Mr Fujita

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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), 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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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 (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

M. B. Eydelman, MD

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 know) K083387

Device Name KOWA nonmyd α-DIII (Type 2)

Indications for Use

KOWA nonmyd α-DIII, fundus camera, is intended for use with retinal image capturing without mydriatic. The retinal image can be stored to an image filing drive through serial interface

Prescription Use X Over-The-Counter Use

(Part 21 CFR 801 Subpart D) AND/OR (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 and Ear, Nose and Throat Devices

510(k) Number K083387

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