5.0 510(k) Summary K091098 AUG 07 2009

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan
Contact:	Akihiro Fujita
Date Summary Prepared:	April 10 , 2009
Device Trade Name:	KOWA GENESIS-Df
Classification name:	CAMERA, OPHTHALMIC, AC-POWERED
Product Code:	HKI

Intended use:
KOWA GENESIS-Df is a device intended to capture and save fundus images with mydriatic.

Comparison:
KOWA GENESIS-Df makes basics structures are the same as that of KOWA GENESIS-D. The reflectance of the reflective mirror of a flash lamp and the transmissivity of the optical pass system of an optical fiber were raised by having added the function of Fluorescent angiography (FA). Moreover, design change of electrical circuit and capacitance were enlarged compared with KOWA GENESIS-D. Therefore, evaluation of light hazard, electrical safety, and EMC was performed, and it was checked that device safety is a level equivalent to KOWA GENESIS-D.

The KOWA GENESIS-Df is similar to the KOWA GENESIS-D 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. Both devices are equipped with highly sensitive CCD cameras, and use a lower flash light intensity than previous cameras requiring film, thereby providing greater user comfort.

Compared to the predicate device, the KOWA GENESIS-Df uses less power during observation by using a visible LED light for observation lighting.

Various weight savings were achieved with the KOWA GENESIS-Df camera to allow the user to be able to hold it in one hand with ease.

The function comparison of KOWAGENESIS-Df and the predicate devices is shown in the comparison table below:

Table 5-1: Predicate Device

Predicate Device	Manufacturer	510(k)No.	Date Cleared
KOWA GENESIS-D	Kowa Company, Ltd.	K050271	Nov. 03, 2005

Table 5-2: Predicate device comparison table

	KOWA GENESIS-Df	KOWA GENESIS-D
Intended use	A hand-held mydriatic retinal camera which captures fundus image.	A hand-held mydriatic retinal camera which captures fundus image.
Use condition	SAME to GENESIS-D	with mydriatic
Picture angle	SAME to GENESIS-D	Horizontal: 30 degree Vertical: 25 degree
Working distance	SAME to GENESIS-D	5mm
Observation	SAME to GENESIS-D	Visual observation
Storage media	SAME to GENESIS-D	Flash memory card
Camera spec.	SAME to GENESIS-D	Color CCD camera 2,000,000 pixels
Image data format	SAME to GENESIS-D	JPEG and uncompressed format
Diopter compensation	SAME to GENESIS-D	−15D～+35D
Observation Light Source	SAME to GENESIS-D	Visible LED 4VA(approx. 1W)
Photographing Light Source	Xenon flash lamp 23WS with improved optical system*	Xenon flash lamp 23WS
Power consumption	150VA	60VA
Weight of Camera unit	approx. 1kg	approx. 1kg

* The maximum rated of the flash bulb currently used is using the KOWA GENESIS-D. For fluorescence photographing function loading, capacity of the power supply was enlarged, inputs energy was enlarged, and amount of luminescence was increased by improving the efficiency of optical systems.

Conclusion:

The KOWA GENESIS-Df is equipped with the same fundamental technology as the predicate devices 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 GENESIS-Df and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

KOWA Company, Ltd.
c/o Mr. Akihiro Fujita
General Manager
4-14, Nihonbashihoncho 3-chome
Chuo-ku, Tokyo
Japan 103-8433

AUG 07 2009

Re: K091098
Trade Name: KOWA Genesis-Df
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: July 3, 2009
Received: July 6, 2009

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.

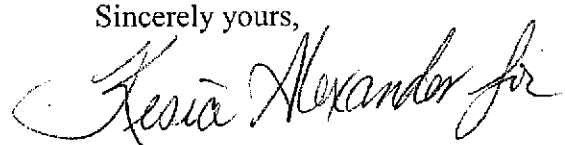
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indication for Use

510(k) Number (if known): K091098

Device Name: KOWA GENESIS-Df

Indication For Use: KOWA GENESIS-Df is a device intended to capture and save fundus images with mydriatic.

Prescription Use ✓ And/Or Over the Counter Use _____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

8/7/2009

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