K050271

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9. Certification
9.1 Summary for Public Disclosure

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan
Contact:	Satohiko Takanashi
Date Summary Prepared:	November 30, 2004
Device Trade Name:	KOWA GENESIS-D
Classification name:	CAMERA, OPTHALMIC, AC-POWERED
Product Code:	HKI

Intended use:

The Kowa hand-held retinal camera, KOWA GENESIS-D is a device intended to capture and save fundus images with mydriatic.

Comparison:

Similar to the KOWA GENESIS, the KOWA GENESIS-D is a mydriatic retinal camera. In comparison with the KOWA GENESIS, it contains a similar optical system, and power supply system, and maintains the same level of safety performance.

The KOWA GENESIS-D is similar to the Nidek Handy NM-100 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-D uses less power during observation by using a visible LED light for observation lighting.

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

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

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Predicate device comparison table

	KOWA GENESIS-D	KOWA GENESIS	Nidek Handy NM-100
Intended use	A hand-held mydriatic retinal camera which captures fundus image.	A hand-held mydriatic fundus camera.	A hand-held non-mydriatic fundus camera which captures images of the retinal electronically.
Use condition	SAME to GENESIS	with mydriatic	without mydriatic
Picture angle	SAME to GENESIS	Horizontal: 30 degree Vertical: 25 degree	30 degree
Working distance	SAME to GENESIS	5mm	8mm (form the examination window to the cornea)
Observation	SAME to GENESIS	Visual observation	5 inch Color LCD
Storage media	SAME to NM-100	35mm film	Flash memory card
Camera spec.	Color CCD camera 2,000,000 pixels	35mm film camera	Color CCD camera 350,000 pixel
Image data format	JPEG and uncompressed format	N/A	JPEG
Diopter compensation	SAME to the both	−15D～+35D	-15D～+35D
Observation Light Source	Visible LED 4VA(approx. 1W)	Halogen lamp 12V, 50W	Infrared LED
Photographing Light Source	Xenon flash lamp 23WS	Xenon flash lamp 150WS	Xenon flash lamp 25WS
Power consumption	60VA	400VA	200VA
Weight of Camera unit	approx. 1kg	approx. 1kg	1.5kg

Conclusion:

The KOWA GENESIS-D 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-D and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kowa Company, Ltd.
c/o Tamas Borsai
Program Manager, Third Party Review Program
TUV Rhelnland of North America, Inc.
North America Headquarters
12 Commerce Road
Newtown, CT 06470

Re: K050271
Trade/Device Name: Kowa Genesis-D Hand-Held Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: October 7, 2005
Received: October 11, 2005

Dear Mr. Borsai:

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 Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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): K050271

Device Name: KOWA GENESIS-D

Indications for Use:

The Kowa hand-held retinal camera, KOWA GENESIS-D is a device intended to capture and save fundus images with mydriatic.

Prescription Use ✓ (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 Ear, Nose and Throat Devises

510(k) Number K050271