K062356

SEP 27 2006

Summary for public disclosure

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-3-3279-7329 Fax: +81-3-3245-1109
Contact:	Satohiko Takanashi, PE
E-mail address:	s-takana@kowa.co.jp

Date summary prepared:	August 11, 2006

Device identification:

Device trade name:	KOWA nonmyd α-D (Type G)
Classification name:	CAMERA, OPTHALMIC, AC-POWERED
Product code:	HKI

Intended use:

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

Comparison:

The KOWA nonmyd α-D (Type D) was chosen as a substantially equivalent device. The predicate device is non-mydriatic fundus camera and they are equipped with highly resolution CCD camera, so it do not require any film and can display images immediately after image capture. Also, because it uses a highly sensitive CCD camera the flash required for filming is reduced compared to previous fundus cameras which use film.

Similar to the predicate device the KOWA nonmyd α-D (Type G) is equipped with a highly sensitive CCD camera so they do not require film and can display images immediately after image capture.

KOWA nonmyd α-D(Type G) has the same picture angle as the predicate device.

A comparison table between the KOWA nonmyd α-D(Type G) and predicate device are provided in Table B and C. The KOWA nonmyd α-D(Type G) has incorporated similar technical characteristics to the predicate device.

K062356

Conclusion:

KOWA nonmyd α-D(Type G) is equipped with the same fundamental technology features, which are equivalent to the predicate device, and also delivers the equivalent level safety and effectiveness. Thus it is concluded that there is no significant difference in the basic functions, safety and effectiveness between KOWA nonmyd α-D (Type G) and the predicate device.

Table A: Predicate device

Predicate Device	Manufacturer	510(k) No.	Date Cleared
KOWA nonmyd α-D (Type D)	Kowa Company, Ltd.	K053026	Nov.10,2005

Table B. Predicate device comparison

	KOWA nonmyd α-D (Type G)	KOWA nonmyd α-D (Type D)
Indications For Use	KOWA nonmyd α-D (Type G) is intended for use with retinal image capturing without mydriatic. The retina image can be stored to an image filing drive through serial interface.	The KOWA nonmyd series, non-mydriatic fundus cameras, are intended for use with retina image capturing. The retinal image can be stored to an external hard disk drive or transferred in other formats through memory card or serial interface depending on the output interface available for each device.
Saved image format	Same	BMP, JPEG
Picture angle	Same	45degree/20degree
Working distance	Same	.30 mm
Working distance detection method	Same	Anterior (Observation) Fundus (Focusing on blight spots)
CCD camera for observation	Same	1/3 inch CCD camera
CCD camera for photographing	2/3 inch 5mega pixels CCD	Type D: 1/2 inch 2.1mega pixels CCD
Observation Display (B/W)	Same	5.6 inch LCD Monitor
Display	Same	Outer Monitor Use
Dioptric compensation	Same	Total -33D to +40D
Focusing	Same	Sprit luminous bars coincidence

K062356

Table C. Predicate Device Comparison

	KOWA nonmyd α-D (Type G)	KOWA nonmyd α-D (Type D)
Observation Light Source	Same	Halogen lamp (Max 12V 100W) with infrared filter
Photographing Light Source	Same	Xenon flash (Max 50WS)
Internal Fixation Navigation	Same	Fixed fixator selecting
Switching light path of observation & photographing	Same	Same pathway, no beam split
Observation light adjustment	Same	Volume adjustment style
Photographing light adjustment	Same	Step adjustment style (5 step)
Camera stand (Base)		
Type	Same	Tabletop; power source built in
Horizontal Movement	Same	Forward/Backward: 40mm Leftward/Rightward: 100mm
Vertical Movement	Same	30mm
Shutter Release	Same	Joystick upper button
Signal outlet	IEEE1394	Type D: USB
Chinrest		
Vertical Movement of chinrest	Same	60mm
External Fixation Targets	Same	Free-arm style (Option)
Compliance with safety standards		
EMC	Same	EN60601-1-2: 2001
Dimension		
Size	Same	Type D:310mm(W)x504mm(D)x548mm(H)
Weight	Same	Type D: 21kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2006

KOWA Company, Ltd.
c/o Satohiko Takanashi, PE
4-14, Nihonbashi-Honcho 3-chome
Chuo-ku, Tokyo, 103-8433 Japan

Re: K062356
Trade/Device Name: Kowa nonmyd α-D (type G) Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: September 11, 2006
Received: September 12, 2006

Dear 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.

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K062356

Device Name: KOWA nonmyd α-D (Type G)

Indications for Use:

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

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) 9/22/2006
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K062356