K980246

MAY 6 1998

510(K)Summary

1.Date Prepared: January 29, 1998

2.Applicant's Name: Canon USA, Inc.
One Canon Plaza.
Lake Success, NY 11042

Mr. Glenn Impal/Mr. Ken Shadoff
Phone: (516)328-5600
Fax. (516)328-5169

3.Model Name: Canon CR6-45NM
86HKI, Non-Mydriatic Retinal Camera, AC Powered
Document Control Number.

4.Predicate Model: Canon CR5-45NM
86HKI, Non-Mydriatic Retinal Camera, AC Powered
Document Control Number. K941234

5.Device Description: CR6-45NM is an improved model of CR5-45NM. CR6-45NM has employed Auto Flash Adjustment and Advanced Internal Fixation Lamp, making operation easier.

5.Intended Use: CR6-45NM is intended to be used for taking pictures of retina of human eye without a mydriatic.

7.Summary of Technological Characteristics: See the attached comparison chart.

K980246

COMPARISON CHART

		CR5-45NM	CR6-45NM
P	Angle of view	45° (37° when S.P switch is ON)	Same
	Actual image size	ϕ 22mm (on 35mm film) ϕ 74mm (on Polaroid film)	Same
R	Min. diameter of pupil required	4.0mm (3.7mm when S.P switch is ON)	Same
F	Working distance(WD)	45mm	Same
	Focusing	By aligning the split lines	Same
O	Data to be printed	Hand-written data	Same
R	Eye fixation lamp	Internal(during observation of retinal image)	Internal(during observation of eye front image and retinal image)
M	Light source for photography	Max. 300WS	Same
A	Working range		
N	Vertical	37mm	Same
	Forward & back	40mm	
	Right & left	100mm	
C	Chin rest(vertically)	70mm	
	External dimension	W325xL480xH585mm	W325xL496xH570mm
E	Weight	Approx. 24kg	Same
Intended use		Taking picture of retina of human eye	Same
Design		See Attachment	See Attachment
Energy	used	300VA	Same
	delivered	NA	Same
Materials		See Attachment	
Target population		General Population	Same
Physical safety		UL544	Same
Compliance with standards		UL544	Same
Biocompatibility		NA	Same
Labeling	Packaging	See Attachment	See Attachment
	Inserts	See Attachment	See Attachment
	Prompts	See Attachment	See Attachment
	Software	Exclusive pre-installed software	Same

K980246

Materials

	CR5-45NM	CR6-45NM
1	ABS resin	Same
2	Aluminum die cast ADC10	Same
	robber NBR	Same
4	ABS resin	Same
5	Aluminum casting AC2A	Aluminum die cast ADC10
6	PBT resin	PC resin
7	Stainless steel stick SUS303BG	Same
8	PBT resin	Same
9	ABS resin	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 6 1998

Mr. Ken Shadoff
Product Safety Engineer
Quality Management Department
Cannon, USA
One Canon Plaza
Lake Success, NY 11042-1198

Re: K980246
Trade Name: Non-Mydriatic Retinal Camera, Model CR6-45NM
Regulatory Class: II
Product Code: 86 HKI
Dated: March 11, 1998
Received: April 28, 1998

Dear Mr. Shadoff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (IF Known): K980246

Device Name: CAMERA, OPHTHALMIC, AC-POWERED

Indications For Use:

Taking pictures of retina of human eye.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980246

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 201.109)

(Optional Format 1-2-96)