JUN - 6 2003

K031629

Section G: Summary

510(k) Summary

Prepared: April 16, 2003

Submitter:

Company Name: Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address: One Canon Plaza
Lake Success, NY 11042
Contact Person: Ms. Sheila Driscoll
Phone Number: (516) 328-5602
Fax Number: (516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CR-DGi
Classification Name:	HKI, Ophthalmic cameras
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CR5-45NM
Classification Name:	86HKI, , Ophthalmic cameras
FDA 510(k) #:	K980246

Description Of Device: CR-DGi is an improved model of CR5-45NM.

Intended Use: CR-DGi is intended to be used for taking pictures of retina of human eye without a mydriatic.

K031629

Appendix D: Substantial Equivalence Comparison

D-2 Table of comparison

			CR6－45NM	CR—DGi
PERFORMANCE	Angle of view		45° (37° when S.P switch is ON)	Same
	Actual image size		ϕ22mm (on 35mm film) ϕ74mm (on Polaroid film)	Same
	Min. diameter of pupil required		4.0mm (3.7mm when S.P switch is ON)	Same
	Working distance (WD)		45mm	Same
	Focusing		By aligning the split lines	Same
	Data to be printed		Hand-written data	None
	Eye fixation lamp		Internal (during observation of eye front image and retinal image)	Internal (during observation of eye front image and retinal image) External
	Light source for photography		Max. 300WS	Same
	Image unit		EOS Digital Camera (with Adapter) 35mm film unit Polaroid film unit 3CCD TV Camera (with Adapter)	EOS Digital Camera
	Working range Vertical Forward & back Right & left Chin rest (vertically)		37mm 40mm 100mm 70mm	Same
	External dimension		W325xL496xH570mm	Same
	Weight		Approx. 24kg	Approx. 23kg
Intended use			Taking picture of retina of human eye	Same
Energy		used	300VA	Same
		delivered	NA	Same
Target population			Optometrist and Ophthalmologist	Same
Physical safety			UL544	Same
Compliance with standards			UL544	Same
Biocompatibility			NA	Same
Labeling		Packaging	Printed model name is changed	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Canon U.S.A., Inc.
c/o Mr. Joseph Murnane
Senior Staff Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
Melville, NY 11747

Re: K031629
Trade/Device Name: Canon Non-Mydriatic Retinal Camera, Model CR-DGI
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: May 27, 2003
Received: May 27, 2003

Dear Mr. Murnane:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications Statement

510(K)Number(if known): K031629

Device Name: CANON NON-MYDRIATIC RETINAL CAMERA CR-DGi

Indications for Use:

Canon Non-Mydriatic Retinal Camera CR-DGi is intended to be used for taking pictures of retina of human eye without a mydriatic.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K031629