510(k) Summary

Prepared: October 11, 2006

JAN 2 3 2007

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:	CF-1
Classification Name:	86HKI, Ophthalmic cameras
Regulatory Class:	Class II
FDA 510(k) #:	To be assigned K063717

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CF-60DSi
Classification Name:	86HKI, Ophthalmic cameras
Regulatory Class:	Class II
FDA 510(k) #:	K041546

Intended Use: CF-1 is intended to be used for taking digital images of retina of human eye with a mydriatic.

Description Of Device: CF-1 is an improved model of CF-60DSi. Canon EOS Digital Camera is mounted with CF-1, can be viewed immediately, making procedures more efficient and many different applications, such as telemedicine and electronic filing.

CF-1's intended use is the same as that of CF-60DSi. However, the differences in design are as follows:

- CF-1 can take images in three modes, such as COLOR, RED FREE, and FLOU.
- CF-60DSi can take images in four modes, such as COLOR, RED FREE, FLOU and ICG.
- ICG digital camera cannot be attached to CF-1.
- CF-1 has 2 variable powers (50//43 degree), where 43 degree is digital magnification. CF-60DSi has 2 optical variable powers (60//40 degree).

CF-1 is equivalent to CF-60DSi in the following respect:

- The optical components and alignment and the mechanical structures of the CF-1 are almost same as the CF-60DSi. Please refer to the CF-1 comparison table provided in this section.

Table of Comparison

		CF-60DSi	CF-1
FDA 510K #		K041546	Proposed Device
PERFORMANCE	Angular field of view	60/40 degree	50/43 degree (digital magnification)
	Actual image size	φ29×22 mm (on sensor array) φ7.5×5.7 (Type 1:on sensor array)	φ15.1×13.7 mm (on sensor array) Not Applicable
	Min. diameter of pupil required	φ5.5mm	φ5.2mm
	Working distance (WD)	45mm	35mm
	Focusing	By aligning the split lines	Same
	Eye fixation lamp	External	Same
	Filter set	Automatic/Manual	Automatic
	Light source for photography	Max. 300WS	Max. 160WS
	Image unit	EOS Digital Camera ICG digital camera (with Adapter)	EOS Digital Camera Not Applicable
	Working range Vertical Forward and back Right and left Chin rest (vertically)	 38mm 70mm 120mm 65mm	 30mm 65mm 110mm 60mm
	Panning	30 degree, right or left	Same
	External dimensions Main unit Power control unit	 W320×D560×H565mm W225×D380×H485mm	 W320×D531×H566mm Not Applicable
	Weight Main unit Power control unit	 Approx.27kg Approx.27kg	 Approx.26kg Not Applicable
Intended use		Taking digital images of retina of human eye with a mydriatic	Same
Energy	used	1000VA	350VA
	delivered	Not Applicable	Same
Target population		Ophthalmologist	Same
Physical safety		UL60601-1	Same
Compliance with standards		UL60601-1	Same
Biocompatibility		Not Applicable	Same
Labeling		Printed model name and electrical ratings are changed. "Rx Only" added to and EMC reference removed from CF-1 rating label.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2007

Canon USA, Inc.
c/o Jeffrey D. Rongero
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
Melville, NY 11747

Re: K063717
Trade/Device Name: Canon Digital Retinal Camera CF-1
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: January 9, 2007
Received: January 10, 2007

Dear Mr. Rongero:

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 Statement

510(K)Number(if known): K063717

Device Name: CF-1

Indications for Use:

The device is intended to be used for taking digital images of retina of human eye with a mydriatic.

Prescription Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off) 1/17/2007
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K063717