JUN 21 2000

K992606

510(k) Summary

Prepared: July 15, 1999

Submitter:

Company Name:	Canon USA, Inc. (U.S. designated agent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Ken Shadoff, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon Laser Blood Flowmeter
Model Name:	CLBF Model 100
Classification Name:	HLI, Ophthalmoscope, AC-Powered
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Heidelberg Engineering Gmbh
Trade Name:	Heidelberg
Model Name:	Retina Flowmeter
Classification Name:	HLI, Ophthalmoscope, AC-Powered
FDA 510(k) #:	K943955

Description Of Device:

The Canon Laser Blood Flowmeter (CLBF) Model 100 allows for fundus observation with velocity measurement of retinal blood flow.

Intended Use:

This device is intended for use in observing patient's fundus (retina) with the information of blood flow (velocity) in a retinal vessel. The information of blood flow is also obtained by CLBF Model 100, and it is intended to help doctor's reading of retinal images.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

Non-clinical Tests:

Software evaluation has been performed to support a claim of substantial equivalence. Documented non-clinical studies have been included to support a claim of substantial equivalence.

Clinical Tests:

A published clinical study was included to support a claim of substantial equivalence.

Comparison with the similar product of the other company (1/2)

Approved product : Heidelberg Engineering, Heidelberg Retina Flowmeter

July 15, 1999

Manufacturer			Canon Inc.	Heidelberg Engineering
product name			Canon Laser Blood Flowmeter CLBF model 100	Heidelberg Retina Flowmeter
Intended use			Fundus observation with retinal blood flow measurement	
specification / function	fundus observation	method	similar to conventional fundus camera with eye drop (through optical finder / on PC monitor (optional))	laser scanning ophthalmoscope with no eye drop (displayed on PC monitor)
		observation angle	30	max. 20x 20
		illumination light	560 - 650 nm Halogen lamp	670 nm / 100 uW laser diode
		diopter compensation range for examinee's eye	-10 - +10 Diopter or more	-12 - +12 Diopter
	velocity measurement	principle	laser Doppler	laser Doppler
		measurement laser	675 nm / max. 300uW (usually 200uW) laser diode	785 nm / 100uW laser diode
		target	blood flow in retinal vessels	blood flow in retinal vessels

Comparison with the similar product of the other company (2/2)

Product Name			Canon Laser Blood Flowmeter CLBF model 100	Heidelberg Retina Flowmeter
specification / function	fundus observation	measurement duration	2 sec for data acquisition	2 sec
		measurement result	given in a real dimension i.e. velocity : [mm/sec], flow rate : [ul/min]	given as relative value
		others	numerically : velocity flow rate vessel diameter graphically : time variation of velocity, flow rate	numerically : velocity, flow, blood volume graphically : perfusion map of retina velocity / flow / volume
anatomical regions			retina (one or both eyes)	same
target population			general population	same
physical safety			limit exposure to laser light	same
compliance with standards			UL 544, IEC 825	unknown
status of device			pending 510(k)	post-amendment device, K943955
dimensions (W x D x H)			main unit : 320 x 560 x 620 power control unit : 230 x 390 x 465	main unit : 300 x 360 x 530 power control unit : 330 x 160 x 125 control panel : 155 x 200 x 100
mass (kg)			main unit : 30 power control unit : 31	main unit : 13 power control unit : 1 control panel : 0.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2000

Ms. Sheila Driscoll
Senior Product Safety Engineer
Quality Management Department
Canon U.S.A., Inc.
One Canon Plaza
Lake Success, NY 11042-1198

Re: K992606
Trade Name: Canon Laser Blood Flowmeter (CLBF) Model 100
Regulatory Class: II
Product Code: 86 HLI
Dated: April 19, 2000
Received: April 20, 2000

Dear Ms. Driscoll:

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) 594-6413. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(K)Number(if known): K992606

Device Name: CLBF MODEL 100

Indications for Use:

Canon Laser Blood Flowmeter CLBF model 100 is intended for use in observing patient's fundus (retina) with the information of blood flow (velocity) in a retinal vessel. The information of blood flow is also obtained by CLBF model 100, and it is intended to help doctors' reading of retinal images.

(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)

Denise L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K992606