K023816

510(k) Summary

NOV 26 2002

Prepared: August 22, 2002

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent/official correspondent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042 U.S.A.
Contact Person:	Sheila Driscoll, Senior Product Safety Engineer
Phone Number:	(516) 328-5602
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Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	FULL AUTO TONOMETER TX-F
Classification Name:	86HKX,Tonometer, AC powered
Classification #:	886.1930
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	TX-10 Tonometer
Classification Name:	86HKX, Tonometer, AC powered
Classification #:	886.1930
FDA 510(k) #:	K963079

Description Of Device:

The Canon FULL AUTO TONOMETER TX-F is a tonometer designed using a non-contact measurement system.
Air puff gently measures the intraocular pressure with the help of a full auto-alignment system.

Intended Use:

The Canon FULL AUTO TONOMETER TX-F is intended to be used for the measurement of intraocular pressure of the human eye.

Technical Characteristics:

Please refer to the attached COMPARISON CHART.

CANON TONOMETER COMPARISON CHART

Model		CANON TONOMETER TX-10	CANON TONOMETER TX-F
Specification	Measuring Range Setting	0-30/0-60mmHg (Automatic)	Same as TX-10
	Alignment Method	Auto Mode Monitor and auto alignment	Full Auto Mode Monitor and auto alignment and Change R/L position
			Auto Mode Same as TX-10
		Manual Mode Monitor with two dots	Manual Mode Same as TX-10
	Increment	1mmHg	Same as TX-10
	Measuring Time	3 millisecond (0.003 second)	Same as TX-10
	Fixation Target	LED(green)	Same as TX-10
	Chin Rest	Power assisted (driving at controller)	Same as TX-10
Safety Mechanism		Software Controlled Stopper	Same as TX-10
Printout Format		R/L,Date,time,avarage,ID, 3 or 10 data for each eye	Same as TX-10
Display		4"(inch)Color LCD	5"(inch)B/W CRT
Dimentions (with×depth×height)mm		Body 299×340×177	280×540×480±15
		Controller 170×183×177	
Weight(kg)		Body 16.0	20.5
		Controller 1.5	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2002

Canon USA, Inc.
Underwriters Laboratories Inc.®
c/o Mr. Kent Donhue
1285 Walt Whitman Road
Melville, NY 11747

Re: K023816
Trade Name: Canon "Full Auto Tonometer TX-F"
Classification Regulation Number: 886.1930
Regulatory Class: II
Product Code: HKX
Dated: November 1, 2002
Received: November 15, 2002

Dear Mr. Donhue:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

K023816

Indications Statement

510(K)Number(if known): _____

Device Name: FULL AUTO TONOMETER TX-F

Indications for Use:

The Canon FULL AUTO TONOMETER TX-F is intended to be used for the measurement of intraocular pressure of the human eye.

(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 K023816