K111710

Section 5: 510(k) Summary

510(k) Summary

SEP 20 2011

Prepared: June 17, 2011

Submitter/Holder:

Company Name:	CANON INC.
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Proposed Device:

Reason For 510(k):	New Model
Trade Name:	CANON INC.
Model Name:	Full Auto Tonometer TX-20P
Classification Name:	HKX, Tonometer and accessories.
FDA 510(k) #:	To be assigned

Predicate Device:

Trade Name:	CANON INC.
Model Name:	Canon Full Auto Tonometer TX-F
Classification Name:	HKX, Tonometer and accessories.
FDA 510(k) #:	K023816

Description of Device:

The Canon Full Auto Tonometer TX-20 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-20 is intended to be used for the measurement of intraocular pressure of the human eye.

Comparison to Predicate:

The TX-20 is substantially equivalent to the predicate device identified previously with regard to intended use, safety and effectiveness.

Performance testing:

The Electrical safety, Electromagnetic compatibility and other performance testings were performed on the TX-20 and the TX-20 complies with applicable standards and guidances. Evaluation performed on the TX-20 demonstrated that it's safe and effective.

Conclusion:

The Performance Data demonstrate that TX-20 is as safe and effective as predicate device, Canon Full Auto Tonometer TX-F. Based on the information in this submission, similarity to predicate device, and the results of our design control activities and non-clinical testing, it is the opinion of CANON INC. that the Full Auto Tonometer TX-20 described in this submission is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

Canon, Inc. – Medical Equipment Group
c/o Mr. Koji Kubo
Manager
Cosmos Corporation
6-5-3 Beaune Honkomagome 2F, Honkomagome, Bunkyo-ku
Tokyo, 113-0021
Japan

SEP 20 2011

Re: K111710
Trade/Device Name: Canon TX-20 Full Auto Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and accessories
Regulatory Class: Class II
Product Code: HKX
Dated: August 30, 2011
Received: August 31, 2011

Dear Mr. Kubo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K111710

Device Name: Full Auto Tonometer TX-20

Indications for Use:

The Canon Full Auto Tonometer TX-20 is intended to be used for the measurement of intraocular pressure of the human eye.

Prescription Use (Part 21 CFR 801 Subpart D)	X	OR	Over-The-Counter Use (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)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K111710