K972212

SEP 10 1997

PTW-New York Corporation
2437 Grand Avenue
Bellmore, New York 11710

510(k) Premarket Notification for PTW T31006 and T31007
Pinpoint type ionization chambers

Manufacturer's 510(k) Summary Certification, 21 CFR 807.92:

1. **Company:**

PTW-New York Corporation
2437 Grand Avenue
Bellmore, New York 11710
(P) 1-516-221-4708
(F) 1-516-221-4329

Contact:

Stephen R. Szeglin
General Manager
PTW-New York Corporation
(P) 1-516-221-4708
(F) 1-516-221-4329

Date of Submission:
June 9, 1997

2. **Trade/Proprietary Name:**
PTW T31006, 0.015 cc Pinpoint type ionization chamber, waterproof,
PTW T31007, 0.005 cc Pinpoint type ionization chamber, waterproof.

Common/Usual Name:
0.015 cc waterproof ionization chamber,
0.005 cc waterproof ionization chamber.

3. **Predicate Device(s):**
PTW T31002, 0.125 cc waterproof ionization chamber, K954165, and
PTW T31003, 0.03 cc waterproof ionization chamber, K954165.

4. **Description of Device(s):**
The PTW T31006 and T31007 are classical waterproof ionization chambers that differ only in the lengths of their respective active volumes. The T31006 is a 0.015 cc ionization chamber with a 5 mm active length and the T31007 is a 0.005 cc ionization chamber with a 2 mm active length. Both chamber volumes are open to the atmosphere, they are waterproof, and they are vented via their connectors. These chambers are constructed of precisely the same materials, are available with a 1 m or 10 m cable for connection to an electrometer, and may be terminated in a variety of standard electrometer connectors (BNT, TNC, PTW M, or BNC banana.

The Pinpoint type ionization chamber, when connected to an appropriate electrometer like the PTW-UNIDOS, K951764, are used to collect beam data from radiation therapy treatment machines.

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5. **Statement of Intended Use:**

The PTW T31006 and T31007 Pinpoint type ionization chambers are intended to be used for the collection of beam data in water, air, or other suitable solid state phantom material from radiation therapy treatment machines. This data is used to completely document the beam characteristics of treatment machines and to establish and maintain an on going treatment machine quality assurance program.

6. **Comparison of Technological Characteristics to the Predicate Devices:**

The indications for use are exactly the same as the predicate devices, the PTW T31002 - 0.125 cc waterproof ionization chamber, and the PTW T31003 - 0.03 cc waterproof ionization chamber, which were both cleared to market by the FDA under K954165, 5 December 1995, as accessories to the PTW MP3 and MP3S Automatic Water Phantom.

The designs are exactly the same.

The manufacturing and testing, process and procedures are exactly the same.

The materials used are the same as in the predicate devices with the exception of the steel electrode.

The specifications are the same as the predicate devices.

The indications for use, design, materials, manufacturing, and specifications of the PTW T31006 and T31007 Pinpoint ionization chambers do not raise any issues with regard to safety and effectiveness.

PTW considers the T31006 and T31007 Pinpoint ionization chambers equivalent in all respects to the predicate devices for radiation therapy beam data acquisition.

Note: Any statement made in conjunction with this Summary regarding substantial equivalence to another product was made in relation to the 510(k) premarket approval process and should not be interpreted as an admission or used as evidence in patient infringement litigation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1997

Stephen R. Szeglin
General Manager
PTW-New York Corporation
2437 Grand Avenue
Bellmore, N.Y. 11710

Re: K972212
PTW T31006 0.015 cc Pinpoint Type Ionization Chamber
PTW T31007 0.005 cc Pinpoint Type Ionization Chamber
Dated: June 9, 1997
Received: June 12, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Mr. Szeglin:

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 requirement, 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) 594-4613. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Premarket Notification for PTW T31006 and T31007
Pinpoint type ionization chambers

June 9, 1997

Premarket Notification
Indication For Use Statement

510(k) Number (if known): Not assigned as of June 9, 1997

Device Name: 0.015 cc Pinpoint type ionization chamber,
0.005 cc Pinpoint type ionization chamber.

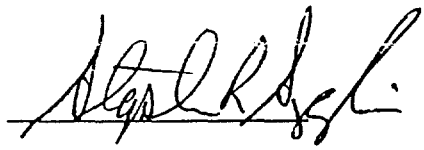
Indications For Use:

High quality ionization chambers, like the PTW T31006 and T31007 Pinpoint type ionization chambers make it possible to routinely measure, record, and document therapeutic amounts of ionizing radiation with an exceptionally high degree of accuracy and precision.

This type of Ionization chamber is intended to be used for the collection of radiation beam data from radiation therapy treatment machines in water, air, or other suitable solid state phantoms. Since the T31006 and T31007 Pinpoint chambers are waterproof, they are ideally suited for measurements of high energy photons and electrons in a water phantom.

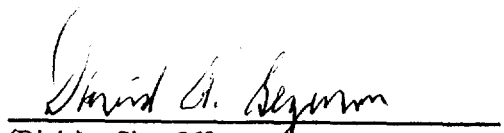
The data acquired with this type of chamber can be used to completely document the beam characteristics of treatment machines, compile radiation beam data over time as part of a quality assurance program, and to establish an initial baseline for the radiation therapy beams generated by the treatment unit.

High quality ionization chambers, like the PTW Pinpoint type chambers, are essential if accurate data from treatment machines that produce therapeutic amounts of ionizing radiation are to be properly monitored.

Signature: 

Typed Name: Stephen R. Szeglin

Date: JUNE 9, 1997



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972212

Prescription Use ✓
(Per 21 CFR 801.109)