JUN 17 1996

K961208

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

PTW 0.6 cc Ionization Chambers
510(k) Submission

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

1. **Company:**

PTW-New York Corporation
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Contact:

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Date of Submission:

March 22, 1996

2. **Trade/Proprietary Name:**

PTW T30004 0.6 cc Farmer type ionization chamber, thimble vent - not waterproof, connector vent - waterproof,

PTW T30005 0.6 cc Farmer type ionization chamber, thimble vent - not waterproof, connector vent - waterproof,

PTW T30001 0.6 cc Farmer type ionization chamber, connector vent - waterproof,

PTW T30002 0.6 cc Farmer type ionization chamber, connector vent - waterproof.

Common/Usual Name:

0.6 cc Farmer type ionization chamber

3. **Predicate Device(s):**

PTW T30001 and T30002 0.6 cc Farmer type ionization chamber, K951764.

4. **Description of Device(s):**

The PTW T30004 and T30005 are classical 0.6 cc Farmer type ionization chambers. These chambers differ only in the type of material their respected thimbles are made of. The T30004 has a graphite thimble and an aluminum stem and the T30005 has a solid water thimble and an aluminum stem. The chambers can be thimble vented, which is not waterproof, or connector vented, which is water proof.

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4. Description of Device(s) (con't):

Both chambers offer 1 or 10 meter cables for connection to an electrometer, and a variety of standard electrometer connectors (BNT, TNC, M, BNC banana).

The connector vented version of the PTW T30001 and T30002 Farmer type ionization chambers are simply a waterproof version of the thimble vented chambers that were cleared to market by the FDA under K951764.

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

5. Statement of Intended Use:

The PTW T30004, T30005, T30001 and T30002 0.6 cc Farmer 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, PTW T30001 and T30002 0.6 cc Farmer type ionization chambers, which were cleared to market by the FDA under K951764.

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 solid water used for the T30005 thimble. For this particular device and its application, solid water is universally accepted as equivalent to PMMA or graphite, which are the materials used in the thimbles of the predicate chambers.

The specifications are the same as the predicate devices.

The indications for use, design, materials, manufacturing, and specifications of the PTW T30004, T30005, T30001, and T30002 do not raise any issues with regard to safety and effectiveness. PTW considers all of these 0.6 cc Farmer type ionization chambers equivalent 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.