

SEP 10 1997

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

510(k) Premarket Notification for PTW T10004 and T42007
MULTIDOS and QC6PLUS

K972211

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

1. Company:

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

Contact:

Stephen R. Szeglin
General Manager
PTW-New York Corporation
(P) 1-516-221-4708
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Date of Submission:

June 9, 1997

2. Trade/Proprietary Name:

PTW T10004, MULTIDOS, Multiple Channel Dosimeter,
PTW T42007, QC6PLUS, Therapy Beam Evaluation System.

Common/Usual Name:

Multiple channel electrometer,
Therapy beam constancy check device.

3. Predicate Device(s):

MULTIDOS:
PTW T10006, MULTIDOS ME48, 48 channel electrometer, K954165, and
Nuclear Associates, 37-702 and 37-703, PC Rainbow, K900932.

QC6PLUS:

Keithley 35300, Tracker™, Therapy Beam Evaluation System, K874893

4. Description of Device(s):

The PTW T10004 MULTIDOS is a field class multiple-purpose multiple-channel electrometer. This device is designed to accurately measure dose, dose rate, charge, and current for photons and electrons in the therapeutic energy ranges. MULTIDOS may be configured as a stand alone 2, 6, or 12 channel electrometer and can be used with suitable ionization chambers and solid state detectors.

The PTW T42007 QC6PLUS is a therapy beam constancy device which may be configured with 6 or 10 individual 0.54 cm³ ionization chambers orthogonally arranged and imbedded in a 5 cm thick PMMA slab. When the QC6PLUS is connected to MULTIDOS, therapy beam parameters like flatness, symmetry, energy stability, and central beam dose are easily monitored.

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5. Statement of Intended Use:

The PTW T10004 MULTIDOS as a stand alone dosimeter is intended to be used to measure the dose delivered to a patient during a radiation therapy treatment. Dose measurements during treatment may be accomplished by using suitable ionization chambers or solid state detectors. Data acquired by MULTIDOS is used to compare and to verify treatment dose to prescribed dose.

The PTW T42007 QC6PLUS cable connects to MULTIDOS and is intended to be used to measure the beam characteristics of radiation therapy treatment machines. Data acquired with the MULTIDOS and the QC6PLUS is used to compile radiation beam data over time as part of a quality assurance program.

6. Comparison of Technological Characteristics to the Predicate Devices:

The indications for use of the MULTIDOS and the QC6PLUS are exactly the same as the predicate devices.

The designs are essentially the same as the predicate devices.

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

The materials used are the same as in the predicate devices.

The specifications are the same as the predicate devices.

The indications for use, design, materials, manufacturing, and specifications of the PTW T10004 MULTIDOS and T42007 QC6PLUS do not raise any issues with regard to safety and effectiveness.

PTW considers the T10004 MULTIDOS and T42007 QC6PLUS equivalent in all respects to the predicate devices for radiation therapy beam measurements.

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 patent infringement litigation.



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, New York 11710

Re: K972211
Multidos Multi Channel Electrometer and
QC6PLUS Constancy Check Device
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

510(k) Number (if known): K972211

Device Name: MULTIDOS AND QC6PLUS
PTW T10004 PTW T42007

Indications For Use:

The PTW T10004 MULTIDOS is a multiple-purpose, multiple-channel electrometer intended to perform a range of measuring tasks in radiation therapy. As a stand alone dosimeter, MULTIDOS is intended to be used to measure the dose delivered to a patient during a radiation therapy treatment. Dose measurements during treatment may be accomplished by using suitable ionization chambers or solid state detectors and are used to compare and to verify treatment dose to prescribed dose.

When connected to the optional QC6PLUS, MULTIDOS is intended to be used to measure the beam characteristics of radiation therapy treatment machines. Data acquired with the MULTIDOS and the QC6PLUS is used to compile radiation beam data over time as part of a quality assurance program.

High quality dosimetry devices like the PTW T10004 MULTIDOS and the optional T42007 QC6PLUS make it possible to routinely measure, record, document and verify therapeutic amounts of ionizing radiation with an exceptionally high degree of accuracy and precision. High quality multiple purpose dosimetry devices are essential if accurate data from treatment machines that produce therapeutic amounts of ionizing radiation are to be properly monitored.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David H. Sykes
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972211

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

