K062817

PTW-New York Corporation
205 Park Ave., Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

510(k) Premarket Notification for the PTW DAVID, an IMRT QC Check Device

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

1. **Company:**

PTW-New York Corporation
205Park Avenue
Hicksville, New York 11801
(P) 1-516-827-3181
(F) 1-516-827-3184

NOV 2 2 2006

Contact:

Richard D. Barker
PTW-New York Corporation
(P) 1-516-827-3181
(F) 1-516-827-3184

Date of Submission:
July 18, 2006

2. **Trade/Proprietary Name:**
PTW DAVID

Common/Usual Name:
IMRT QC check device

3. **Predicate Device(s):**
PTW QC6Plus, K972211

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

The PTW DAVID system MLC-29 is a transparent, segmented, multi-wire ionization chamber with 37 wires or segments. It is designed for operation in medical linear accelerators with 29 multi-leaf collimator pairs.

The PTW DAVID system MLC-80 is a transparent, segmented, multi-wire ionization chamber with 40 wires or segments. It is designed for operation in medical linear accelerators with 40 multi-leaf collimator pairs.

The PTW DAVID system MLC-120 and MLC-80 are transparent, segmented, multi-wire ionization chamber with 80 and 40 wires or segments. They are designed for operation in medical linear accelerators with 60 or 40 multi-leaf collimator pairs.

The software for the PTW DAVID is for recording or logging measurement data only.

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510(k) Premarket Notification for the PTW DAVID, an IMRT QC Check Device

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

5. **Statement of Intended Use:**

The PTW DAVID is a transparent, multiple wire or multiple segment ionization chamber intended to be used for QC verification measurements and documentation of the leaf positions and doses from medical accelerators used for IMRT radiotherapy sequences. Data acquired by the PTW DAVID is used to compare and to verify a treatment dose to a prescribed dose and to compile radiation beam data, consistency, over time as part of a quality assurance program.

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

The technological specifications of the PTW DAVID meet or exceed that of the predicate device since both devices are produced by the same manufacturer.

Safety and effectiveness between the Dosimetry Diode and the predicate device is not an issue since the PTW DAVID is designed in full accordance with the applicable sections of the following standards:

IEC 60601-1:	Medical Electrical Equipment - Part 1: General requirements for safety and essential performance,
IEC 60601-1-2:	Medical Electrical Equipment - Electromagnetic emissions compatibility – Requirements and tests
UL 60601-1:	US Medical Equipment –Part 1: General requirements safety and essential performance.

The manufacturing, testing, and the process and procedures that are used to produce the PTW DAVID and the predicate device are in full compliance with our ISO 9001 certification. Both devices are CE marked with CE 0124.

It is our opinion that the indications for use, design, materials, manufacturing, and specifications of the PTW DAVID do not raise any issues with regard to safety and effectiveness

PTW considers the PTW DAVID to be substantially equivalent to the predicate device.

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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NOV 2 2 2006

Mr. Richard D. Barker
Official Correspondent
PTW- New York Corporation
205 Park Avenue
NICKSVILLE NY 11801

Re: K062817
Trade/Device Name: PTW-DAVID
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 12, 2006
Received: September 26, 2006

Dear Mr. Barker:

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 (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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K062817

Device Name: PTW DAVID

Indications For Use:

The PTW DAVID is a transparent multiple wire or multiple segment ionization chamber with attached electronics. It is intended to be used as an IMRT QC check device to make verification measurements and provide documentation of the leaf positions and doses from medical accelerators used for IMRT radiotherapy sequences. Data acquired by the PTW DAVID is used to compare and to verify a treatment dose to a prescribed dose and to compile radiation beam data, consistency, over time as part of a quality assurance program.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062817

(Optional Format 3-10-98)