

Subject: 510(k) Summary of Safety and Effectiveness Information for the Standard Imaging DoseView 3D

Proprietary Name: Standard Imaging DoseView 3D

DEC 27 2010

Device Name Classification(s):

Primary: Medical Charged-Particle Radiation Therapy System (accessory to)
Secondary: Radiologic Quality Assurance Instrument,
Radiation Therapy Simulation System

Device Panel: Radiology

Device Classification(s):

Primary: Class II – 21CFR892.5050 – IYE
Secondary: Class II – 21CFR892.1940 – LHO
Class II – 21CFR892.5840 – KPQ

Predicate Devices:

Primary: Computerized Medical Systems, Inc., DynaScan Radiation Beam Data Acquisition System - 510(k) K854880
Secondary: PTW – New York Corp., MP3 Automatic Water Phantom - 510(k) Number K954165

Contact Person: Raymond Riddle, PE, RAC,
Chief Regulatory Officer

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The DoseView 3D system is a 3-axis, water phantom scanning system intended to easily and accurately, measure and analyze pulsed photon and electron radiation from a linear accelerated-based radiation therapy system or continuous radiation from a radioactive source-based radiotherapy system. This data is then often used in support of a radiation treatment planning system. It is comprised of a water tank, electrometer, radiation detector(s), motion controller, controlling software, master pendant and lift/reservoir cart. It is a prescription device intended to be used by a trained medical physicist. The general uses of the DoseView 3D include:

- Acceptance testing and/or commissioning of a radiation therapy or radiotherapy system.
- Quality assurance measurements to identify and minimize the sources of uncertainty and error in the radiation therapy system, radiotherapy system or radiation treatment planning system.
- Collection of dose depth data for radiation treatment planning system use.
- Completion of clinical dosimetry protocols and calibrations.

Standard Imaging acquired the product technology, controlling software and labeling for the DoseView 3D System from Computerized Medical Systems, Inc. Previously, Computerized Medical Systems had successfully distributed their DynaScan Radiation Beam Data Acquisition System and further supported their system until the company was acquired by Elekta AB. Thus, the new Standard Imaging DoseView 3D is the logical update and evolution of the original Computerized Medical Systems DynaScan Radiation Beam Data Acquisition System. That system was cleared by FDA via a 510(k) premarket notification.

The Standard Imaging DoseView 3D was designed to comply with the applicable portions of the following voluntary product related standards:

- ISO 13485: Quality Management Systems
- ISO 14971: Risk Management
- IEC 60601-1, plus amendments: Medical Electrical Equipment
- IEC 60601-1-2, plus amendments: EMC/EMI
- IEC 60601-1-4: Programmable Systems
- IEC 60731: Dosimeters with Ionization Chambers as used in Radiotherapy
- IEC 61217: Radiotherapy Equipment Coordinates, Movements and Scales
- EN 980: Symbols
- EN 1041: Manuals

The Standard Imaging DoseView 3D has been verified and validated at Standard Imaging. These activities addressed software testing, installation testing, acceptance testing, quality assurance testing, data collection, calibrations and shipment testing related to the device. Additionally, the DoseView 3D was successfully evaluated by the following clinical beta sites:

- Turville Bay MRI & Radiation Oncology Center, Madison, WI
- UW Hospitals & Clinics, Madison, WI
- ATC/Tokyo Metropolitan University, Tokyo, Japan

The Standard Imaging DoseView 3D has been deemed to meet its predetermined design specifications, risk analysis and validation objectives.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Raymond T. Riddle, PE, RAC
Chief Regulatory Officer
Standard Imaging, Inc.
3120 Deming Way
MIDDLETON WI 53562-1461

DEC 27 2010

Re: K103193

Trade/Device Name: DoseView 3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy device
Regulatory Class: II
Product Code: IYE
Dated: October 27, 2010
Received: October 29, 2010

Dear Mr. Riddle:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

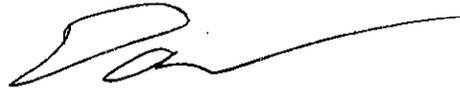
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html>.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103193

Device Name: DoseView 3D

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Indications For Use:

The DoseView 3D system is a 3 axis, water phantom scanning system intended to easily and accurately, measure and analyze pulsed photon and electron radiation from a linear accelerated-based radiation therapy system or continuous radiation from a radioactive source-based radiotherapy system. This data is then often used in support of a radiation treatment planning system. It is comprised of a water tank, electrometer, radiation detector(s), motion controller, controlling software, master pendant and lift/reservoir cart. It is a prescription device intended to be used by a trained medical physicist. The general uses of the DoseView 3D include the following:

- Acceptance testing and/or commissioning of a radiation therapy or radiotherapy system.
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- Completion of clinical dosimetry protocols and calibrations.

Prescription Use X
(Part 21 CFR 801 Subpart D)

and/or

Over-the-Counter-Use _____
(Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103193

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