K102583

510(k) Safety and Effectiveness Summary

NOV - 2 2010

Submitter: Oncology Data Systems, Inc.
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Contact: Vincent Ruminer

Date: August 30, 2010

Trade Name: **Mucheck V9.0**

Common Name: Dose Validation Software

Classification Panel: Radiology

Classification Name: Medical Charged Particle Radiation Therapy System(Accessory)
21 CFR 892.5050 (class II)

Performance Standards: none established under section 514

Substantial Equivalence:

Device Name	510(K) Number
MUCheck Monitor Unit Validation (V8 for Gamma Knife)	K091602

Description:
The MU Check Program is a software program that is designed to operate on an IBM compatible personal computer in a Windows environment. It has been designed to operate either in a stand alone mode independent of the treatment planning system or to import plans from the treatment planning system. It does not connect to or control any radiation hardware device. MUCheck performs dose calculations to verify the dose calculated by the primary radiation treatment planning system. The functionality ot the MUCheck program is being extended to include calculations for the Tomotherapy Hi Art system, by this submission.

Substantial Equivalence Summary:

Intended Use:
The intended use for the MU Check program is the same as for the predicate devices: to calculate a dose for the purpose of validating a dose previously calculated by the primary treatment planning system. The functionality of the MUcheck program is being extended by adding an optional module(TomoCheck) by this submission. The TomoCheck module will allow the MUcheck program to perform point dose calculations for treatment plans created by the TomoTherapy Hi Art system. The intended use is as a quality assurance tool only and not as a treatment planning device.

In a radiation therapy department quality assurance is an important part of patient care. The ability to provide a secondary check for the primary dose calculation is part of good treatment protocol as well being a recommendation by Task Group 40. MU Check provides this very important quality assurance function.

Technological Characteristics:
The technological characteristics are the same as for the predicate devices. MUCheck was designed to operate in a windows environment using both mouse and keyboard.

Non-clinical tests:
Verification and validation test plans were completed in accordance with Oncology Data Systems procedures and GMP guidelines. A Hazard Analysis was completed and hazards were resolved as appropriate. All system specifications were met and testing performed to demonstrate substantial equivalence. The non-clinical tests were conducted using the treatment planning system and MU Check/TomoCheck module. The test results all matched very closely which supports the claim of substantial equivalence. See Figure 6.0 in section 6 for comparison summary.

Summary of Clinical Testing:
Clinical testing was not required to demonstrate substantial equivalence or safety and effectiveness.

Conclusions:
Based upon the technological characteristics, intended use, and non-clinical tests, MUCheck is substantially equivalent to the predicate device. The documentation submitted for review supports this claim.

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. Vincent Ruminer
President
Oncology Data Systems, Inc.
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OKLAHOMA CITY OK 73159

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Re: K102583
Trade/Device Name: MuCheck V9
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical image communications device
Regulatory Class: II
Product Code: IYE
Dated: August 30, 2010
Received: September 8, 2010

Dear Mr. Ruminer:

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): K102583

Device Name: **MuCheck V9**

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Indications For Use:

MuCheck is an independent computer based verification of the monitor unit or dose calculated by the primary radiation treatment planning system.

The intended use of the **MuCheck** software has been extended to include an optional module, **MuCheck/TomoCheck** to independently verify the dose for single point that has been previously calculated by the Tomotherapy Hi Art treatment planning system or other points as determined by the physicist.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

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