K091602

JUN 18 2009

510(k) Safety and Effectiveness Summary

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

Date: May 18, 2009

Trade Name: **Mucheck** Gamma-Knife QA Check

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 (V4 for IMRT)	K012227
MuCheck Monitor Unit Validation (V7 for Brachy)	K061152
Leksell GammaPlan	K061540

Description:
The Gamma-Knife QA 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 Gammaknife treatment planning system or to import plans from the GammaKnife treatment planning system. It does not connect to or control any radiation hardware device. Gamma Knife QA Check performs dose calculations to verify the dose calculated by the primary GammaKnife radiation treatment planning system.

Substantial Equivalence Summary:

Intended Use:
The intended use for the Gamma-Knife QA Check program is the same as for the predicate devices: to calculate a dose for the purpose of validating a dose previously calculated by a the

primary GammaKnife treatment planning 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. Gamma Knife QA Check provides this very important quality assurance function.

Technological Characteristics:
The technological characteristics are the same as for the predicate devices. Gamma-Knife QA Check 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 GammaKnife treatment planning system and Gamma-Knife QA Check. 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, Gamma Knife QA Check 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
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Oncology Data Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services
1394 25th Street NW
BUFFALO MN 55313

Re: K091602
Trade/Device Name: MuCheck V8
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 1, 2009
Received: June 3, 2009

Dear Mr. Job:

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 (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091602

Device Name: **MuCheck V8**

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, **Gamma-Knife QA Check** to independently verify the dose for single or multiple points that have been previously calculated by the Gamma Knife 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 Reproductive, Abdominal and Radiological Devices
510(k) Number K091602