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K980904

510(k) Safety and Effectiveness Summary

Submitter: Medical Dosimetry Services, Inc.
12401 Riverview Rd.
Oklahoma City, Ok. 73173
tel. (405) 745-2188
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Contact: Gregory G. Miller, Vice-President
Date: March 6, 1998

Trade Name: muCheck - Monitor Unit Validation Program

Common Name: Monitor Unit Validation Program

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: K & S Associates, PC Setup Program
510(k) K 914698

1071693 10 45
FOA/CDRH/OGE/DHC

Description:

The muCheck Monitor Unit Validation 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 on a stand alone mode independent of any radiation treatment planning system. It does not connect to or control any radiation hardware device.

Substantial Equivalence Summary:

Intended Use:

The intended use for the muCheck Monitor Unit Validation Program is the same as for the predicate device: to calculate a monitor unit or timer setting for the purpose of validating a monitor unit or timer setting previously calculated by a primary radiation treatment planning system or hand calculation. 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 monitor unit calculation is part of good treatment protocol as well being a recommendation by Task Group 40. MuCheck provides this very important quality assurance function.

Safety and Effectiveness:

The staff at Medical Dosimetry Services includes a certified medical dosimetrist with over 20 years of experience. The computer programming and design has been provided by a systems analyst with over 20 years of experience in the design and development of systems. The combined expertise as well as conformance to the GMP regulations helped to insure that the finished product is safe and effective to use.

A comprehensive users manual available as a hard copy as well as on-line, provides extensive documentation and tutorial for the user. Initial system startup and training is provided on-site as part of the service provided by Medical Dosimetry Services.

Technological Characteristics:

The technological characteristics are mostly the same as for the predicate device with the main exception being that the predicate device was designed to operate in a DOS environment as a character based menu driven system. MuCheck was designed to operate in a windows environment using both mouse and keyboard.

Non-clinical tests:

The non-clinical tests were conducted using both the predicate device and muCheck. In addition each test was further validated using a treatment plan which provide a monitor unit or hand calculation. The test results all matched very closely which supports the claim of substantial equivalence. See Figure 6.0 in section 6 for comparison summary.

Beta Clinical Testing:

The results received and summarized from the beta testing conducted in St. John Hospital support the claim of substantial equivalence. See Figure 6.1 in section 6 for comparison summary.

Conclusions:

Based upon the technological characteristics, intended use, non-clinical tests, as well as clinical tests, muCheck is substantially equivalent to the predicate device. The documentation submitted for review supports this claim.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Gregory Miller
Medical Dosimetry Services, Inc.
12401 Riverview Road
Oklahoma City, OK 73173Re: K980904
muCheck - Monitor Unit Validation Program
Dated: March 6, 1998
Received: March 10, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Miller:

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 requirements, 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/dsma/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

