K 020027

OCT 0 8 2002

FOCUS Radiation Treatment Planning System
Proton Planning
510(k) Summary of Safety and Effectiveness

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Contact Person:	Michael A. Parsons - Director - Quality Assurance and Regulatory Affairs
Date Summary Prepared:	December, 2001
Device Trade Name:	FOCUS Radiation Treatment Planning System
Device Common Name:	Radiation Treatment Planning System
Device Classification:	System, Simulator, Radiation Therapy per 21CFR892.5840
Substantial Equivalence:	Varian ProtonVision (K000922 & K002312)

Device Description: The FOCUS Radiation Treatment Planning System accepts a) patient diagnostic imaging data from CT and MR scans, or from films, and b) "source" dosimetry data, typically from a linear accelerator. The system then permits the user to display and define (contour) a) the target volume to be treated and b) critical structures which must not receive above a certain level of radiation, on these diagnostic images.

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Based on the prescribed dose, the user, typically a Dosimetrist or Medical Physicist, can then create multiple treatment scenarios involving the type, number, position(s) and energy of radiation beams and the use of treatment aids between the source of radiation and the patient (wedges, blocks, ports, etc.). The FOCUS system then produces a display of radiation dose distribution within the patient, indicating not only doses to the target volume but to surrounding tissue and structures. The "best" plan satisfying the prescription is then selected, one which maximizes dose to the target volume while minimizing dose to surrounding healthy volume. The parameters of the plan are output in hard-copy format for later reference and for placement in the patient file.

Previously, for situations where external beam therapy was to be used, either Electron and/or Photon radiation beams could be selected.. These were delivered by a linear accelerator whose output characteristics are input to the treatment planning system prior to beginning planning.

This Premarket Notification addresses the addition of a third type of radiation beam - Proton. The algorithm for calculating dose was provided by the Massachusetts General Hospital (MGH), based on their years of experience at the Harvard Cyclotron Lab. In addition to providing the algorithm, MGH also worked with CMS in its implementation. Software developers at MGH were trained on the CMS software development process to permit them to create code directly for use in FOCUS. As the final step, MGH provided the verification testing to assure the algorithm had been implemented correctly, measuring calculated dose against measures. A FOCUS RTP System with proton planning capability is now in clinical use at the Northeast Proton Therapy Center.

Device Intended Use: The FOCUS RTP System with will continue to be used to create treatment plans for any cancer patient for whom external beam radiation therapy or brachytherapy has been prescribed.

The system will calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient for a given treatment plan set-up.

Summary of Technological Characteristics Compared to Predicate Devices: The Proton Planning algorithm described in this 510(k) consists of modules "added-on" to the existing FOCUS Radiation Treatment Planning System previously cleared under K915691 in February, 1995, K973936 in June, 1998 and K002147 in October, 2000.

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Summary of Clinical Testing: Actual testing in a clinic was not performed as part of the development of this feature. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of the device.

Summary of Non-Clinical Testing: Algorithm test cases were written and executed to assure the system is calculating dose correctly for proton treatment plans. The results of testing on the Proton Algorithm feature can be found in the Validation of the CMS Proton Treatment Planning System for Treatments In Large Field Beam Line at the Harvard Cyclotron Laboratory (HCL) authored by Skip Rosenthal of MGH. This document is included in Tab 15 of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Mr. Michael A. Parsons
Director, Quality Assurance and
Regulatory Affairs
Computerized Medical Systems, Inc.™
1145 Corporate Lake Drive
ST LOUIS MO 63132

Re: K020027
Trade/Device Name: FOCUS Radiation Treatment Planning System with Proton Planning Capability
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: August 22, 2002
Received: August 23, 2002

Dear Mr. Parsons:

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); 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.

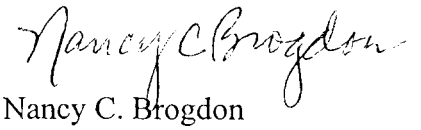
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



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

Enclosure

Statement of Indication for Use

510(k) Number: K020027

Device Name: FOCUS Radiation Treatment Planning System with Proton Planning Capability

Indication for use: The FOCUS RTP System consists of CMS-developed software running on UNIX-based operating systems and off the shelf hardware including computers and various computer peripherals (digitizing tablet, printer/plotter, etc.).

The intended use of FOCUS RTP System is to provide radiation treatment planning capability, for both external beam and brachytherapy sources, to satisfy the prescription of a Radiation Oncologist. The resultant treatment plan is to be evaluated, modified as necessary, approved and delivered by qualified medical personnel. Operation of the system is identical to FOCUS systems cleared under previous Premarket Notifications with the exception the user can now select a third type of external beam particle for therapy (protons) in addition to the earlier two particles (electrons and photons)..

Concurrence of the Center for Devices and Radiological Health,
Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

per 21 CFR 801.109

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020027