

K 973936

JUN 1 1998

**510(k) Summary of Safety and Effectiveness Data  
FOCUS Stereotactic Radiosurgery Treatment Planning System**

**Submitter Name:** Computerized Medical Systems, Inc.

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Regulatory Affairs

**Date Summary Prepared:** September, 1997

**Device Trade Name:** FOCUS Stereotactic Radiosurgery Treatment Planning  
System

**Device Common Name:** Radiation Treatment Planning System

**Device Classification:** System, Simulator, Radiation Therapy per 21 CFR  
892.5840 (Class II)

**Substantial Equivalence:** ADAC Pinnacle<sup>3</sup> APEX Stereotactic Radiosurgery  
Planning System - K951581  
Nucletron PLATO SRS Stereotactic Radiosurgery  
System - K940001  
RSA XKNIFE3 Stereotactic Radiosurgery System -  
K953482

**Device Description:** The FOCUS Radiation Treatment Planning System accepts a) patient diagnostic imaging data from CT or MR scans or from films and b) "source" dosimetry data, typically from a linear accelerator. The system then permits the user to

**510(k) Summary of Safety and Effectiveness Data**  
**FOCUS Stereotactic Radiosurgery Treatment Planning System**  
**Page 2 of 3**

define a target volume to be treated based on these diagnostic images. Based on the prescribed dose, the user, typically a Dosimetrist or Medical Physicist, can then create multiple treatment scenarios involving the 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 dose 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.

The software addition to add stereotactic radiosurgery treatment planning capability to FOCUS was developed at the Mallinckrodt Institute of Radiology of the Washington University School of Medicine in St. Louis, Missouri. The addition of Stereotactic Radiosurgery Therapy Planning capability to the system is a logical extension of the original intended use of the system. Stereotactic Radiosurgery is actually a sub-set of standard treatment planning in that it accepts the same inputs in the same formats as that for general planning. One significant, simplifying difference is that, in Stereotactic Radiosurgery Therapy, there are no treatment aids between the source and the patient. All therapy is performed using what are referred to as "open fields". A second difference is the introduction of "headframes" which, as the name implies, attach to the patients head and provide a unique patient coordinate system. The significant issue introduced here is one of coordinate transformation between the headframe and the patient diagnostic imaging data from the CT or MR machine. The system has been validated and marketed to support only the BRW headframe for CT or MR scans.

**Device Intended Use:** The Stereotactic Radiosurgery system is to be used to create a treatment plan for any patient with single or multiple lesions of the brain and for whom radiation therapy 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 Stereotactic Radiosurgery Treatment Planning capability described in this 510(k) has been designed as an "add-on" to the existing FOCUS Radiation Treatment Planning System previously cleared under K915691 in February, 1995. The FOCUS System with Stereotactic Radiosurgery Planning capability incorporates no technological characteristics not currently existent in the predicate Stereotactic Radiosurgery devices.

**510(k) Summary of Safety and Effectiveness Data**  
**FOCUS Stereotactic Radiosurgery Treatment Planning System**  
**Page 3 of 3**

The FOCUS System supports all Linear Accelerators, has 3-D visualization capabilities and can perform both 2-D and 3-D treatment planning. Beam's Eye View (BEV) presentation is available as is a Time/MU calculator. All predicate systems, and FOCUS, use some form of the Ratio Tissue Air Ratio (RTAR) Algorithm to calculate dose. Likewise, all systems run under UNIX on a RISC-based processor workstation. The FOCUS System, unlike most of the predicate devices, has been validated only for use with the Brown-Roberts-Wells (BRW) headframe (there are at least four more on the market) and it does not have image fusion capabilities (the ability to map a MR scan onto a CT scan to obtain better imaging data of soft tissue).

**Summary of Non-clinical Tests:** Seven categories of tests were performed to evaluate the performance of the system: 1) Transfer of CT and MR Images, 2) Verification of Coordinate Transformation Algorithm, 3) Fiducial Marker Localization Verification, 4) Verification of Accuracy of Linear and Spherical Rulers and Checking of Image Pixel Size Detection, 5) Verification of Target Points In Different Software Modules of the System, 6) Verify Alignment of Isodoses with Image Anatomy and 7) Verification of Accuracy of the Dose Calculation Algorithm. This last test was performed by verifying system outputs against calculated and measured data collected especially for this project. The Coordinate Transformation verification was performed against a current marketed device.

**Conclusions From Non-Clinical Tests:** All testing provided results which met the criteria set. The system has been judged to be substantially equivalent to predicate devices and safe and effective for clinical use in the planning of Stereotactic Radiosurgery therapy situations using the BRW headframe. Normal QA of treatment planning activities, including review of the plans by a Medical Physicist and a Radiation Oncologist/Neurosurgeon prior to their use, is recommended.

**Summary of Clinical Tests:** Clinical testing was not performed as part of the development of this feature by the Mallinckrodt Institute of Radiology of the Washington University School of Medicine in St. Louis, MO. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.



JUN 1 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Michael A. Parsons  
Director, Quality Assurance &  
and Regulatory Affairs  
Computerized Medical Ssystem (CMS)  
1195 Corporate Lake Drive  
St. Louis, MO 63132

Re: K973936  
FOCUS Stereotactic Radiation Treatment  
Planning System  
Dated: October 8, 1997  
Received: October 15, 1997  
Regulatory class: II  
Procode: IYE 90, CFR 892.5050

Dear Mr. Parsons:

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

JUN | 1998

## Statement of Indication for Use

510(k) Number: K973936

**Device Name:** FOCUS Stereotactic Radiosurgery Treatment Planning System

**Purpose:** To calculate and display, both on-screen and in hard-copy, either two- or three-dimensional radiation dose distributions within a patient diagnosed as having single or multiple brain lesions based on user-defined radiation treatment plan parameters.

**Function:** The FOCUS Radiation Treatment Planning System accepts a) patient diagnostic imaging data from CT or MR scans or from films and b) "source" dosimetry data for a linear accelerator. The system then permits the user to define a target volume to be treated based on these diagnostic images. Knowing the prescribed dose, the user, typically a Dosimetrist or Medical Physicist, can then create multiple treatment scenarios involving the number, position(s), shape (achieved by use of treatment aids such as wedges, blocks, and ports between the source of radiation and the patient) and energy of the radiation beams. The FOCUS System then produces a display of radiation dose distribution within the patient, indicating not only dose 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 tumor 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.

The addition of Stereotactic Radiosurgery Therapy Planning capability to the system is a logical extension of the original intended use of the system. Stereotactic Radiosurgery is actually a sub-set of standard treatment planning in that it accepts the same inputs in the same formats as that for general planning. One significant difference is that, in Stereotactic Radiosurgery Therapy, there are no treatment aids between the source and the patient. All therapy is performed using what are referred to as "open fields". One new item is the introduction of "headframes" which, as the name implies, attach to the patients head, enhance target immobilization, and provide a unique patient coordinate system. The significant issue introduced here is one of coordinate transformation between the headframe and the patient diagnostic imaging data from the CT or MR machine. The system has been validated and marketed to support only the Brown-Roberts-Wells (BRW) headframe for CT or MR scans.

One difference in delivery of treatment between Stereotactic Radiosurgery and other Treatment Planning is the number of therapy sessions required to deliver the prescribed dose. In stereotactic radiosurgery, the total prescribed dose is typically delivered in a single treatment. For therapy to target volumes in other locations of the anatomy, treatment is typically broken into multiple (20-30) fractions. While this change in therapy delivery introduces no significant change in the treatment planning system, it does increase the amount of patient risk resulting from an incorrect treatment plan. For

**Statement of Indication for Use**  
**(continued from Page 5-1)**

patients receiving fractionated therapy, checks of dose received by the patient are made weekly and any mistake in the plan or delivery may be corrected by raising or lowering the delivered dose over the remaining fractions of therapy. For patients undergoing only one session of radiation, once a mistake is made involving lesion overdose, it cannot be adjusted.

**Target Population:** The Stereotactic Radiosurgery system is to be used to create a treatment plan for any patient with single or multiple lesions of the brain and for whom radiation therapy has been prescribed. Patient demographics are not an issue in creating the treatment plan.

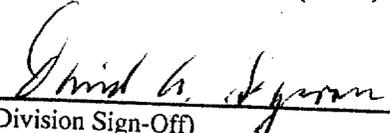
**Intended Environment for Use:** The System is typically used in an office setting within a hospital/clinic. It is not located in the same room as the Linear Accelerator or other source of radiation. There is no need for physical connection between the source of the radiation and the Treatment Planning System.

**Claims for the device:** The FOCUS Stereotactic Radiosurgery Treatment Planning System will provide displays, both on-screen and in hard-copy format, of the radiation dose distributions for a given beam set-up(s) defined by the treatment planner. No claims of dose calculation accuracy, accuracy for CT localization, or center of radiation versus actual center of the lesion is indicated.

**Substantial Equivalence:** The system is substantially equivalent to at least three currently legally marketed devices. It is a subset of these devices, having no features not already found on one or more of the systems. See Section 7 of this Premarket Notification for details of Substantial Equivalence determination.

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

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K973936

Prescription Use  OR Over the Counter Use

per 21 CFR 801.109