DEC 0 5 2001

K013112

510(k) Summary of Safety and Effectiveness
Computerized Medical Systems Premarket Notification
FOCAL CT Simulation (FOCAL SIM)

Submitter Name:	Computerized Medical Systems, Inc.
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Contact Person:	Michael A. Parsons - Director - Quality Assurance and Regulatory Affairs
Date Summary Prepared:	September, 2001
Device Trade Name:	FOCAL Workstation
Device Common Name:	Accessory to Radiation Treatment Planning System
Device Classification:	System, Simulation, Radiation Therapy per 21CFR892.5840
Substantial Equivalence:	Picker International Acqsim Simulator/Localizer - K923851 GE Advantage Sim - K951830 ADAC Advantage Sim - K993923

Device Description: (See Section 7 of this submittal for a more detailed Device Description). The FOCAL Workstation was initially cleared for marketing under K981535. (At that time, the device was referred to as the *FOCUS Pilot Contouring Workstation*. However, by the time the Premarket Notification was cleared, the CMS Marketing Department had selected another trade name.)

The initial release of the product had, as its intended use, the remote contouring of patient outlines, structures and tumors as part of radiation therapy planning. The FOCAL

Workstation was designed to work with our FOCUS Radiation Treatment Planning (RTP) System which was initially cleared for marketing under K915691 and most recently under K002147. The task of contouring, typically performed by the Radiation Oncologist, is the most time-consuming task in radiation therapy planning and requires a minimum of computer capability. It was our goal to free up the higher powered UNIX-based RTP Workstation for performing the more calculation-intensive activities of treatment planning by moving the contouring to a remote device. This remote device was a Personal Computer loaded with the most common Microsoft products (Windows 95, Windows 98, Windows NT) with the FOCAL contouring software running on that platform. When contouring was complete, the information was returned to the RTP System to continue the treatment planning process.

The first release of FOCAL contained only manual contouring capability and was given the trade name of "FOCAL Ease". The second release enhanced the users ability to contour by adding the capability for fusion of CT and MR images as well as providing an autosegmentation capability. This added functionality was given the trade name "FOCAL Fusion".

A later release of FOCAL software provided the capability to view the results of treatment planning performed earlier on the FOCUS RTP System. This included the ability to view isodose distributions as well as Dose Volume Histograms (DVH's) and Digitally Reconstructed Radiographs (DRR's). This was given the name "FOCAL Vue" and provided the Oncologist a remote capability to view and compare alternate treatment plans and select the one which best satisfied her/his prescription.

All of these development efforts were performed per the CMS software development process as described in the initial Premarket Notification clearance. This included in-house validation testing to assure clinical efficacy and safety.

The subject of this Premarket Notification is the addition of the ability to perform CT simulation on the FOCAL workstation, a feature we call "FOCAL Sim". This addition goes beyond the contouring of patient targets or viewing of treatment planning results into a more active role in the treatment planning process. For a description of the CT simulation process, refer to Section 7 of this submittal.

Device Intended Use: The FOCAL Workstation will continue to be used for patient contouring and viewing of treatment plan outputs. With this new software it will also be able to perform CT simulations and forward this information to the RTP System for dose calculation.

Summary of Technological Characteristics Compared to Predicate Devices: The CT Simulation capability described in this 510(k) will be a software module "added-on" to the existing FOCAL Workstation previously cleared under K981535 in April, 1999. The FOCAL System with CT Simulation capability incorporates no technological characteristics not currently in the predicate CT Simulation devices.

The FOCAL System supports the most popular CT Scanners as well as the three most common linear accelerators (Varian, Siemens and Philips/Elekta).

Summary of Clinical Testing: Clinical testing was not performed as part of the development of this feature. Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness. This software merely takes some of the tasks previously performed on the RTP System and allows them to be performed on the FOCAL Workstation.

Summary of Non-Clinical Testing: The testing performed by CMS and our results can be found in Section 9 of this submittal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2001

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

Re: K013112
Trade/Device Name: FOCAL CT Simulation (CT Sim)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: September 14, 2001
Received: September 18, 2001

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: K013112

Device Name: FOCAL Workstation with CT Simulation Capability

Indication for use: The FOCAL workstation software is a computer software package intended to be used as an accessory to a radiation treatment planning system.

FOCAL Sim is intended to permit CT simulation to be performed on the FOCAL workstation. The CT scan is read into the radiation treatment planning system and then sent to the FOCAL workstation. On FOCAL, the user is able to identify patient isocenters, place treatment beams and identify beam modifiers (blocks, wedges, etc.). This information is then passed back to the radiation treatment planning system for storage and documentation of the resultant treatment plan and calculation of patient dose based on this information. The resultant plan is to be evaluated, modified as necessary, approved and delivered by qualified medical personnel.

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

Nancy C. Brogdon

(Division Sign-Off)
Division of [illegible], Abdominal,
and Radiological Devices
510(k) Number K013112