4/2/99

K981535

510(k) Summary of Safety and Effectiveness
FOCUS *Pilot* Contouring Workstaion

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Date Summary Prepared:	April, 1998
Device Trade Name:	FOCUS *Pilot* Contouring Workstation
Device Common Name:	Picture Archiving and Communication System (PACS)
Device Classification:	Digital Image Communication System - Radiology Panel 90 LMD - Class II
Substantial Equivalence:	Base Ten Systems uPACS Version 1.7 PACS System - K961160 Applicare Medical Imaging BV RadWorks Medical Imaging Software - K962699 Olicon Imaging Systems O2-Workstation Software K973959

Device Description: The FOCUS *Pilot* Contouring Workstation ("the CWS") is designed to be used in conjunction with the FOCUS Radiation Treatment Planning.System (K915691). The CWS (the "client") relocates the time-consuming task of image contouring from the RTP System (the "server") and permits it to be done remotely on a workstation designed solely for contouring. This frees the RTP System for performance of dose calculation and display, treatment plan comparison, source file maintenance and other tasks associated with radiation treatment planning.

Device Intended Use: Image contouring is the most time-consuming of the tasks performed by the treatment planning team and, historically, when contouring was in process, the RTP system was unavailable for any other task. In addition, the Radiation Oncologist performing the contouring had to work in the treatment planning area rather than in her/his office or other remote location within the hospital/clinic. With the CWS, this contouring can now be performed at a low-cost workstation (PC-based rather than UNIX-based) connected to the site Local Area Network. This, in turn, also makes the RTP system more available to the Dosimetrist to do treatment planning and review.

The CWS will accept patient image data (CT slices) from the FOCUS RTP System and stores them on its hard drive prior to recalling them for contouring. The CWS provides the user tools with which to review the images and contour and label tumor volumes and critical structures. Patient demographic data, in addition to that entered at the RTP System, is also able to be entered at this workstation. After this contouring has been performed, the images are stored on the PC hard drive prior to being returned to the RTP system for subsequent use in treatment planning. The Contouring Workstation does no treatment planning, and does not accept plan information for display and/or modification. Screen capture printing is available from the CWS.

Summary of Technological Characteristics Compared to Predicate Devices: The FOCUS *Pilot* Contouring Workstation has been designed to work only with the FOCUS Radiation Treatment Planning System previously cleared under K915691. It is not intended for use with any other RTP system and it is not intended to accept images (CT slices) directly from a scanner or via secondary capture. All images must be loaded and accepted in the FOCUS RTP System before they become available to the CWS for contouring. In all other respects, it operates in a manner very similar to the predicate Picture Archiving and Communications System (PACS) devices to which we are claiming substantial equivalence. The CWS acts as a "client" with the RTP System acting as the "server". The CWS workstation is the ubiquitous WinTel PC arrangement with the client running Windows 95 or Windows NT. Communication between client and server is via TCP/IP. The CWS does no lossy image compression as some of the predicate device do.

The CWS provides the capability of image distribution for review and annotation at locations convenient for the Radiation Oncologist. Access to the images is controlled via passwords which are stored in the RTP System (the same method as used when contouring is performed on the RTP System today).

The CWS introduces no new hazards that are not presented by existing PACS systems nor does it introduce new hazards for the FOCUS RTP System. The use of standard hardware, software and communication protocols, combined with avoidance of lossy compression of images, assures a mature system design and relatively hazard-free environment.

Additionally, after contoured images are transferred back to the RTP system and treatment planning is performed, the results go through three sets of quality checks by treatment planning professionals: the Dosimetrist who created the plan, the Medical Physicist who reviews the plan including the dose calculations for both the tumor and critical structures, and the Radiation Oncologist who first wrote the prescription for the radiation therapy and who also did the tumor contouring. These steps further reduce the likelihood of any possible hazards introduced by the use of the CWS going unnoticed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

Michael A. Parsons
Computerized Medical Systems, Inc.
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St. Louis, MO 63132

Re: K981535
FOCUS Pilot Contouring Workstation
Dated: January 20, 1999
Received: February 8, 1999
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number: K981535

Device Name: FOCUS *Pilot* Contouring Workstation

Indications for Use: The FOCUS *Pilot* Contouring Workstation permit contouring of patient tumors and critical structures on images (CT slices) at a workstation remote from the FOCUS Radiation Treatment Planning System. Images are drawn from the FOCUS RTP System, contoured and then returned to the FOCUS RTP System for completion of the treatment planning activity.

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981535

Prescription Use ✓ OR Over the Counter Use ____
per 21 CFR 801.109