K102216

August 4, 2010

XiO RTP System – Proton Spot Scanning
Premarket Notification (510(k))
Summary of Safety and Effectiveness

OCT 1 2010

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the XiO RTP System – Proton Spot Scanning 510(k). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution.

PREMARKET NOTIFICATION INFORMATION

1. Product Information:
   - a. Product Trade Name: XiO RTP System
   - b. Release Version Number: Proton Spot Scanning added in release 4.61
2. Classification Information:
   - a. Classification Name system: Medical charged-particle radiation therapy
   - b. Common/Usual Name: Radiation Treatment Planning System
   - c. Product Classification: Class II
   - d. Product Code: MUJ
   - e. Reference: 21 CFR 892.5050
   - f. Review Panel: Radiology
3. Establishment Information:
   - a. Submitter: Computerized Medical Systems, Inc.
   - b. Submitter Address: 13723 Riverport Dr. , Suite 100
Maryland Heights, MO 63043
   - c. Establishment Number: 1937649
   - d. Contact: Kathryn Stinson, RA Specialist
   - e. Contact Phone: 314-993-0003
   - f. Contact Fax: 314-993-1175

PREDICATE DEVICE INFORMATION

The XiO RTP System with Proton Spot Scanning functionality is substantially equivalent to the following devices that the Food and Drug Administration (FDA) has cleared for distribution and are currently being actively marketed in the United States. XiO is substantially equivalent to these products in intended use and safety and effectiveness.

1. XiO RTP System
   Computerized Medical Systems, Inc.
   K092132

2. Eclipse Treatment Planning System
   Varian Medical Systems
   K091492

XIO INTENDED USE

The XiO RTP System is 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.

DESCRIPTION OF THE PRODUCT

The XiO 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) the target volume, which is the structure to be treated, and critical structures, or organs-at-risk, to which radiation dose must be limited.

Based on the dose prescribed, 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 XiO system produces a display of radiation dose distribution within the patient, indicating doses to the target volume and critical structures. Appropriate clinical personnel select the plan that they believe most effectively maximizes dose to the target volume while minimizing dose to critical structures. The parameters of the plan are output in hard-copy format for later reference placed in the patient file.

This Premarket Notification addresses the addition of the Proton Spot Scanning. XiO provides the user with the ability to choose between multiple dose calculation algorithms, selecting the algorithm most appropriate for the given clinical scenario. More accurate

dose computation increases the probability that disease will be effectively treated and decreases the probability of undesirable side effects. No algorithm produces a perfectly accurate description of dose distribution; all algorithms have limitations, which are generally well understood and documented in scientific literature.

CMS received 510(k) clearance for the addition of proton planning capability to XiO in 2002. This feature extends proton planning functionality, giving the user the ability to create proton treatment plans that involve a series of small proton beams for which dose and monitor units are calculated and displayed individually. This allows users to create intensity modulated radiation therapy (IMRT) plans with protons, as discussed in more detail in section 11 of this submission. The proton spot scanning feature includes a new pencil beam dose calculation algorithm.

LEVEL OF CONCERN

Item 4b of Table 1 in the FDA Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices asks, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems...." XiO does not directly control the linear accelerator that delivers the radiation. Once completed, plans are reviewed and approved by qualified clinicians and may be subject to quality assurance practices before treatment actually takes place. There is no automatic link between the XiO software and the linear accelerator. However, should a flaw in the treatment plan escape the notice of the qualified professionals using the XiO system, serious injury or death could result. Therefore, we believe XiO to be of major level of concern.

SUMMARY OF CLINICAL TESTING

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Algorithm testing was performed to compare calculated against measured doses to ensure dose calculation accuracy. In addition, clinically oriented validation test cases were written and executed in-house by CMS customer support personnel. The product was deemed fit for clinical use.

SUMMARY OF NON-CLINICAL TESTING

Verification tests were written and executed to ensure that the system is working as designed. Pass/fail requirements and results of this testing can be found in the XiO Verification Test Report, which is included in section 18 of this submission. XiO successfully passed verification testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathryn Stinson
Regulatory Affairs Specialist
Computerized Medical Systems, Inc.
13723 Riverport Drive, Suite 100
MARYLAND HEIGHTS MO 63043

OCT 1 2010

Re: K102216
Trade/Device Name: XiO RTP System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ and LHN
Dated: August 4, 2010
Received: August 6, 2010

Dear Ms. Stinson:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

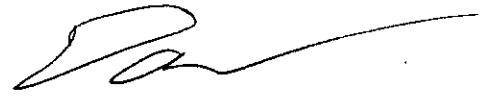
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K102216

Device Name: XiO RTP System

Indication For Use:

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Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mark D O'Rourke for David G. Brown
Division Sign-Off

510(k) K102216