

SEP 24 2009

July 10, 2009

**XiO RTP System – Monte Carlo
Premarket Notification (510(k))
Summary of Safety and Effectiveness**

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the XiO RTP System - Monte Carlo Premarket Notification (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 | Monte Carlo added in release 4.50.00 |

2. Classification Information:

- | | |
|---------------------------|---|
| a. Classification Name | Medical charged-particle radiation therapy system |
| 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 Associate |
| e. Contact Phone | 314-993-0003 |
| f. Contact Fax | 314-993-1175 |

PREDICATE DEVICE INFORMATION

The XiO RTP System with Electron Monte Carlo dose calculation algorithm 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.
K032762
2. Eclipse Treatment Planning System
Varian Medical Systems
K071760
3. Oncentra Masterplan
Nucletron Corporation
K081281

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 Electron Monte Carlo dose calculation algorithm. 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.

The addition of the Monte Carlo dose calculation algorithm gives users a new option for electron treatment plans. The algorithm represents the state of the art in radiation treatment planning and is widely recognized as the most accurate method currently available for computing the dose delivered by a beam of high-energy electrons.

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 submittal. XiO successfully passed verification testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 24 2009

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

Ms. Kathryn Stinson
Regulatory Affairs Associate
Computerized Medical Systems, Inc.
13723 Riverport Dr. Suite 100
MARYLAND HEIGHTS, MISSOURI 63043

Re: K092132
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
Dated: July 10, 2009
Received: July 15, 2009

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 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); medical device reporting (reporting of medical

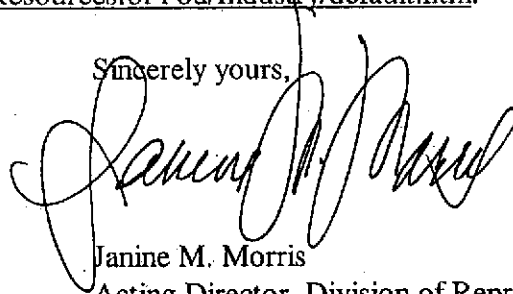
Page 2 –

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

K092132

Device Name: XiO RTP System

Indication For 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.

Prescription Use X
(21 CFR Part 801 Subpart D)

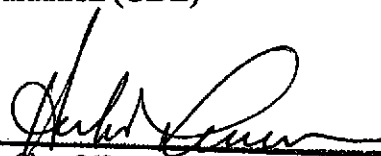
And/Or

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)

Division Sign-Off



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) _____

510(k) Number _____

K092132