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510(k) Summary of Safety & Efficacy & Level of Concern Statement

Monaco 510(k)

Submitter Name:	Computerized Medical Systems, Inc.
Submitter Address:	1145 Corporate Lake Drive St. Louis, MO 63132-1716
Submitter Phone:	314 993 0003
Submitter Fax:	314 993 0075
Contact Person:	Kathryn Stinson – Regulatory Affairs Associate or Michael A. Parsons - Director - Regulatory Affairs
Date Summary Prepared:	July 12, 2007
Device Trade Name:	Monaco RTP System
Device Common Name:	Radiation Treatment Planning System
Device Classification:	Medical charged-particle radiation therapy system per 21CFR892.5050
Substantial Equivalence:	Pinnacle 3 RTP System (K041577); XiO RTP System (K032762); Focal Workstation (K013112); Peregrine RTP System (K993675); Nulcetron Oncentra Masterplan (K031349)
Level of Concern & Rationale*:	Major

OCT 1 ' 2007

*Per FDA document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.

4b of Table 1, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems...." Monaco 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 Monaco software and the linear accelerator. However, should a flaw in the treatment plan escape the notice of the qualified professionals using the Monaco system, serious injury or death could result. Therefore, we believe Monaco to be of major level of concern.

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Device Description: Monaco uses local biological measures for optimization to create intensity modulated radiation therapy (IMRT) plans using Multileaf Collimators.

Device Intended Use: The Monaco system is used to create treatment plans for any cancer patient for whom external beam intensity modulated radiation therapy (IMRT) 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.

The Monaco product line is intended for use in radiation treatment planning using generally accepted methods for contouring, image manipulation, simulation, image fusion, plan optimization and QA and plan review.

Summary of Technological Characteristics Compared to Predicate Devices: Like Pinnacle, Monaco uses biological-based optimization in addition to dose-to-volume optimization and supports MLCs. The Monaco system also includes all functionality found in our Focal Workstation, which is used as an accessory to RTP systems and includes CT simulation and image fusion capabilities. Monaco uses Monte Carlo and Pencil Beam algorithms like those used in the predicate devices. The primary distinguishing characteristic of Monaco is that it is limited to IMRT planning using MLCs.

The verification testing performed on Monaco incorporated the same pass/fail criteria and the same algorithm accuracy requirements as those used to evaluate the XiO RTP System and the Focal Workstation.

A detailed comparison can be found in section 12 of this submittal.

Summary of Clinical Testing: Clinical trials were not performed as part of the development of this feature. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since measured data can be used for testing such that no human subjects are exposed to risk. Clinically oriented validation test cases were written and executed in-house by CMS customer support personnel. On-site validation testing was also performed by a small group of customers, using actual patient data. Monaco was deemed fit for clinical use.

Summary of Non-Clinical Testing: Verification tests, including algorithm test cases, 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 Monaco Verification Test Report and the Algorithm Test Report, both of which are included in section 18 of this submittal. Monaco successfully passed both verification and algorithm testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2008

Mr. Michael A. Parsons
Regulatory Affairs Associate
Computerized Medical Systems
1145 Corporate Lake Drive
ST. LOUIS MO 63132

Re: K071938
Trade/Device Name: Monaco RTP System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: July 12, 2007
Received: July 13, 2007

Dear Mr. Parsons:

This letter corrects our substantially equivalent letter of October 1, 2007.

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 (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 continue 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 Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Statement of Indication for Use
Monaco 510(k)

The Monaco system is used to create treatment plans for any cancer patient for whom external beam intensity modulated radiation therapy (IMRT) 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.

The Monaco product line is intended for use in radiation treatment planning using generally accepted methods for contouring, image manipulation, simulation, image fusion, plan optimization and QA and plan review.

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

Prescription Use X OR Over the Counter Use _____
per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071938