JUN 2 4 2011

K110730

June 14, 2011

Monaco RTP System
Premarket Notification (510(k))
Summary of Safety and Effectiveness

INTRODUCTION

This document summarizes the safety and effectiveness information contained within this Premarket Notification. 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 — Monaco RTP System
   - b. Release Version Number — DCAT feature added in rel. 3.0.0
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 Specialist
   - e. Contact Phone — 314-993-0003
   - f. Contact Fax — 314-993-1175

PREDICATE DEVICE INFORMATION

The Monaco RTP System with dynamic conformal (DCAT) functionality is substantially equivalent to the following devices that the FDA has cleared for distribution and are currently being actively marketed in the United States.

1. Monaco RTP System
   Computerized Medical Systems, Inc.
   K091179

2. ERGO++RTP System
   Computerized Medical Systems, Inc.
   K080601

3. Eclipse Treatment Planning System
   Varian Medical Systems
   K102011

MONACO INTENDED USE

The Monaco system is used to make treatment plans for patients with prescriptions for external beam radiation therapy. The system calculates dose for photon treatment plans and displays, on-screen and in hard-copy, two- or three-dimensional radiation dose distributions inside patients for given treatment plan set-ups.

The Monaco product line is intended for use in radiation treatment planning. It uses generally accepted methods for:

- contouring
- image manipulation
- simulation
- image fusion
- plan optimization
- QA and plan review

DESCRIPTION OF THE PRODUCT

Monaco is a radiation treatment planning system that first received FDA clearance in 2007 (K071938). The modified system received clearance in 2009, when Volumetric Modulated Arc Therapy (VMAT) planning capability was added (K091179). The Monaco system accepts patient diagnostic imaging data and "source" dosimetry data

from a linear accelerator. The system then permits the user to display and define (contour) the target volume to be treated and critical structures which must not receive above a certain level of radiation on these diagnostic images.

Based on the prescribed dose, the user, a Dosimetrist or Medical Physicist, can create multiple treatment scenarios involving the number, position(s) and energy of radiation beams and the use of a multileaf collimator (MLC) between the source of radiation and the patient to shape the beam. The Monaco system then produces a display of radiation dose distribution within the patient, indicating doses to the target volume and surrounding structures. The "best" plan satisfying the prescription is then selected, one that maximizes dose to the target volume while minimizing dose to surrounding healthy volumes.

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...." 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.

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 section 18 of this submission. Monaco successfully passed verification testing.

SUBSTANTIAL EQUIVALENCE COMPARISON

Table 5-1 compares Monaco with Dynamic Conformal capability to its predicate devices. A more detailed discussion of substantial equivalence is contained in Section 12 of this submission.

Table 5-1: Substantial Equivlaence to Predicate Devices

	Monaco w/DCAT Functionality	Monaco (w/VMAT) (K091179)	ERGO++ (K080601)	Eclipse TPS (K102011)
Intended Use and Indications for Use				
Contouring	Yes	Yes	Yes	Yes
Dose Calculation	Yes	Yes	Yes	Yes
Plan Optimization	Yes	Yes	Yes	Yes
Image Manipulation & Fusion	Yes	Yes	Yes	Yes
CT Simulation	Yes	Yes	No	Yes
QA/Plan Review	Yes	Yes	Yes	Yes
Brachytherapy	No	No	No	Yes
Statement specifies that system is for IMRT only	No	Yes	No	No
Basic System: Technological Characteristics				
Dose Calculation Algorithms	Monte Carlo (photon) & Pencil Beam (optimization only)	Monte Carlo (photon) & Pencil Beam (optimization only)	Pencil Beam	Pencil Beam, Electron Monte Carlo, Convolution Superposition
Local Biological Measure Optimization	Yes	Yes	No	Yes
MLC Support	Yes	Yes	Yes	Yes
Support of Other Treatment Aids	No	No	Yes	Yes
Support for Dynamic Delivery Methods	Yes	Yes	Yes	Yes
Operating System	Windows	Windows	Linux	Windows
DICOM RT Support	Yes	Yes	Yes	Yes
Modalities Supported: Full RTP Workflow	Photon Only	Photon Only	Photon Only	Electron, Photon, Proton
Modalities Supported: Partial Workflow*	Electron, Photon, Proton	Electron, Photon, Proton	N/A	Electron, Photon, Proton
New Features: Technological Characteristics				
Includes Dynamic Conformal Capability	Yes	No	Yes	Yes
Stereotactic Localization	No	No	Yes	Yes
Support for Cone-Based Stereotactic	No	No	Yes	Yes

*A partial workflow would include only the functions of Monaco that are shared with Focal, such as contouring, simulation, and plan review. Clinicians who use only the Focal functions within Monaco are using a partial workflow that does not include IMRT optimization or dose calculation.

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

JUN 24 2011

Ms. Kathryn Stinson
Regulatory Affairs Specialist
Elekta, Inc., CMS Software
13723 Riverport Drive, Suite 100
MARYLAND HEIGHTS MO 63043

Re: K110730
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: May 10, 2011
Received: May 12, 2011

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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): K110730

Device Name: Monaco RTP System

Indication for Use:

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Prescription Use _X_ **And/Or** **Over the Counter Use ____**
(21 CFR Part 801 Subpart D) **(21 CFR Part 801 Subpart C)**

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

Concurrence of CDRH, OIVD

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110730