K132971

NOV 2 0 2013

September 20, 2013

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

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the Monaco RTP System 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	Monaco
	b. Release Version Number	Release 5.0
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	IMPAC 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	314-993-0075

PREDICATE DEVICE INFORMATION

The Monaco RTP System 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. Monaco is substantially equivalent to these products in intended use and safety and effectiveness.

1. Monaco RTP System
   IMPAC Medical Systems, Inc.
   K110730

2. ERGO++
   IMPAC Medical Systems, Inc.
   K080601

3. Eclipse Treatment Planning System
   Varian Medical Systems, Inc.
   K102011

4. Oncentra
   Nulcetron Corporation
   K121448

MONACO INTENDED USE/INDICATIONS FOR 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 and electron 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) and again when Dynamic Conformal Arc planning was added (K110730). 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 beam modifiers 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. Validation testing involved simulated clinical workflows, and algorithm testing, described in detail in section 20, which validated the accuracy of dose calculation functions using a simulated clinical setup. 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. Over 500 test procedures were executed, including tests to verify requirements for new product functionality, tests to ensure that risk mitigations function as intended, and regression tests to ensure continued safety and effectiveness of existing functionality. Monaco passed testing and was deemed safe and effective for its intended use.

	Monaco w/new features	Monaco (K110730)	ERGO++ (K080601)	Eclipse TPS (K102011)	Oncentra (K121448)
Intended Use and Indications for Use					
Contouring	Yes	Yes	Yes	Yes	Yes
Dose Calculation	Yes	Yes	Yes	Yes	Yes
Plan Optimization	Yes	Yes	Yes	Yes	Yes
Image Manipulation & Fusion	Yes	Yes	Yes	Yes	Yes
CT Simulation	Yes	Yes	No	Yes	Yes
QA/Plan Review	Yes	Yes	Yes	Yes	Yes
Brachytherapy	No	No	No	Yes	Yes
Technological Characteristics					
Dose Calculation Algorithms	Monte Carlo (electron & photon), Collapsed Cone (photon), Pencil Beam (optimization only)	Monte Carlo (photon) & Pencil Beam (optimization only)	Pencil Beam	Pencil Beam, Monte Carlo (electron) Acuros XB & AAA (photon), proton eye algorithm	Monte Carlo (electron), Collapsed Cone (photon), Pencil Beam
Calculation and display of standard ized uptake value for contouring on PET images	Yes	No	No	Yes	No
Local Biological Measure Optimization	Yes	Yes	No	Yes	No
MLC Support	Yes	Yes	Yes	Yes	Yes
Support for Other Treatment Aids	Yes	No	Yes	Yes	Yes
Support for Dynamic Delivery Methods	Yes	Yes	Yes	Yes	Yes
Operating System	Windows	Windows	Linux	Windows	Windows
DICOM RT Support	Yes	Yes	Yes	Yes	Yes
Modalities Supported: Full RTP Workflow	Photon & Electron	Photon Only	Photon Only	Electron, Photon, Proton	Electron, Photon

Modalities Supported: Partial Workflow*	Electron, Photon, Proton	Electron, Photon, Proton	N/A	Same as above	N/A
Can be used for stereotactic treatment planning	Yes	Yes	Yes	Yes	No
Stereotactic Localization	No	No	Yes	Yes	No
Support for Cone-Based Stereotactic	Yes	No	Yes	Yes	No

- **It is possible to configure Monaco for limted functionality such as image fusion, contouring and simulation, not including IMRT optimization or dose calculation. Customers can purchase a "simulation package" that does not include the ability to optimize or calculate dose.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 20, 2013

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

Re: K132971
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: September 20, 2013
Received: September 23, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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 contact 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. 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,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132971

Device Name: Monaco RTP System

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k) K132971