IMPAC Medical Systems, Inc.                                   July 7, 2015
℅ Ms. Kathryn Stinson
Regulatory Affairs Specialist
13723 Riverport Drive, Suite 100
MARYLAND HEIGHTS MO  63043

Re: K151233
    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 7, 2015
    Received:  May 8, 2015

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Acting 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)*

K151233

Device Name
Monaco RTP System

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)        ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

# 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 5.10
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        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.
   K132971

2. AdvantageSim MD
   GE Healthcare
   K132944

## 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), when Dynamic Conformal Arc planning was added (K110730), and most recently when the

system's intended use was expanded to include electron treatment planning, among other changes (K132971). 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. The Monaco system supports 3D conformal planning, IMRT, and Dynamic Conformal. It supports inverse and forward planning workflows.

## 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, described in detail in section 20. 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 600 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 (K132971) | AdvantageSim MD (K132944) |
|---|---|---|---|
| **Intended Use and Indications for Use** | | | |
| Contouring | Yes | Yes | Yes |
| Dose Calculation | Yes | Yes | No |
| Plan Optimization | Yes | Yes | No |
| Image Manipulation & Fusion | Yes | Yes | Yes |
| CT Simulation | Yes | Yes | Yes |
| QA/Plan Review | Yes | Yes | No |
| Brachytherapy | No | No | No |
| **Technological Characteristics** | | | |
| Dose Calculation Algorithms | Monte Carlo (electron & photon), Collapsed Cone (photon), Pencil Beam (optimization only) | Monte Carlo (electron & photon), Collapsed Cone (photon), Pencil Beam (optimization only) | N/A |
| Calculation and display of standardized uptake value for contouring on PET images | Yes | Yes | No – Display only |
| Local Biological Measure Optimization | Yes | Yes | No |
| Support for various treatment aids | Yes | Yes | Yes |
| Support for Dynamic Delivery Methods | Yes | Yes | No |
| Operating System | Windows | Windows | Linux |
| DICOM RT Support | Yes | Yes | Yes |
| Modalities Supported: Full RTP Workflow | Photon & Electron | Photon & Electron | Not a full RTP system |
| Modalities Supported: Partial Workflow* | Electron, Photon, Proton | Electron, Photon, Proton | Electron, Photon |
| Can be used for stereotactic treatment planning (including cone-based) | Yes | Yes | Unknown |
| Creates specialty images: MIP, MinIP, Avg | Yes | No | Yes |

- **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.**