Elekta, Inc
% Ms. Kathryn Stinson
Senior Regulatory Affairs Engineer
13723 Riverport Drive, Suite 100
MARYLAND HEIGHTS MO 63043

December 4, 2018

Re: K183037
Trade/Device Name: Monaco RTP System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: October 30, 2018
Received: November 1, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183037

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K183037

October 30, 2018

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 5.40
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: Elekta, Inc.
   - b. Submitter Address: 13723 Riverport Dr., Suite 100
Maryland Heights, MO 63043
   - c. Establishment Number: 1937649
   - d. Contact: Kathryn Stinson, Principal RA Engineer
   - e. Contact Phone: 314-993-0003
   - f. Contact Fax: 314-812-4496

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
   Elekta, Inc.
   K151233

2. ViewRay Treatment Planning and Delivery
   ViewRay Inc.
   K102915

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), again when Dynamic Conformal Arc planning was added (K110730), and electron planning, support for stereotactic cones, and SUV calculation were added (K132971). Finally, specialty image creation was added in 2015 (K151233). A 510(k) was filed in 2017 for the addition of carbon ion planning. The 510(k) was withdrawn because there was no hardware cleared for the US market capable of delivering carbon ion plans. Monaco's carbon ion planning functionality remains licensed off and inaccessible to US users.

Since the 2015 510(k) clearance, IMPAC Medical Systems, Inc. merged with Elekta, Inc., both wholly owned subsidiaries of Elekta AB. There were no changes in location, personnel, or quality system as a result of the merger. However, the name of the manufacturer for Monaco as changed from IMPAC Medical Systems, Inc, to Elekta, Inc.

The Monaco system accepts patient 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 beam modifier (MLC, block, etc.) 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 clinican 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 using actual patient data, such as patient images, described in detail in section 20. Algorithm testing verified the accuracy of the new dose calculation algorithm in Monaco 5.40 using the same test methods as the predicate version of Monaco. Pre-defined pass/fail criteria were also equivalent to that of the predicate, K151233. Equivalent accuracy was demonstrated, and the product was deemed substantially equivalent and 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. Verification testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System standard, IEC 62304 Software Life Cycle standard, and ISO 14971 Risk Management Standard, as was the predicate version, K151233. Quality System procedures goverening the testing process, including pre-defined pass/fail criteria, were equivalent to procedures used in the testing of the previous Monaco version cleared under K151233. Conformity to the same pass/fail criteria as the predicate indicated that Monaco 5.40 was substantially equivalent in safety and effectiveness. Monaco 5.40 was deemed safe and effective for its intended use.

	Monaco for Elekta Unity MR-Linac	Monaco (K151233)	ViewRay Treatment Planning & Delivery System (K102915)
Intended Use and Indications for Use			
Contouring	Yes	Yes	Yes
Dose Calculation	Yes	Yes	Yes
Plan Optimization	Yes	Yes	Yes
Image Manipulation & Fusion	Yes	Yes	Yes
CT Simulation	Yes	Yes	Yes
QA/Plan Review	Yes	Yes	Yes
Integrated Planning and Delivery Software	The Elekta MR-Linac system uses Monaco for planning and the MOSAIQ OIS for delivery. The products were designed to work together and tested in an integrated environment to ensure seamless interoperability.	No	The ViewRay system is branded as a single device that handles both planning and delivery.
Technological Characteristics			
Dose Calculation Algorithms	Monte Carlo (electron & photon), Collapsed Cone (photon), Pencil Beam (optimization only), GPUMCD for MR-linac	Monte Carlo (electron & photon), Collapsed Cone (photon), Pencil Beam (optimization only)	Monte Carlo
Calculates dose for MR-Linac (including magnetic field, coils & cryostat)	Yes (GPUMCD algorithm)	No	Yes
Calculation and display of standardized uptake value	Yes	Yes	Unknown
Local Biological Measure Optimization	Yes	Yes	No
Support for various treatment aids	Yes	Yes	Yes
Support for Dynamic Delivery Methods	Yes (conventional linacs only, not for MR-linac environment)	Yes	No
Operating System	Windows	Windows	Windows
DICOM RT Support	Yes	Yes	Yes
Modalities Supported: Full RTP Workflow	Photon, Electron	Photon, Electron	Photon only