Elekta Solutions AB
% Melinda Smith
Director, Regulatory Affairs & Quality - Americas
Elekta, Inc.
400 Perimeter Center Terrace NE Suite 50
ATLANTA GA 30346

February 23, 2023

Re: K223233
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: January 26, 2023
Received: January 27, 2023

Dear Melinda Smith:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.02.23 14:51:34 -05'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223233

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, electron, and proton 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.

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TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

	Elekta Solutions AB Kungstensgatan 18 Box 7593 Stockholm, SE SE10393
Contact:	Melinda Smith, MS, RAC, CBA Melinda.Smith@elekta.com
Establishment Registration #:	3015232217
510(k) Number:	K223233
Date Prepared:	14 October 2022

II. DEVICE

Trade Name:	Monaco Radiation Therapy Planning (RTP) System
Product Classification:	Class II
Common Name:	Radiation Treatment Planning System
Regulation Number:	21 CFR § 892.5050
Regulation Description:	Medical charged-particle radiation therapy system
Product Code:	MUJ

III. PREDICATE DEVICE

Predicate Device: Monaco RTP System (K213787)

IV. DEVICE DESCRIPTION

The Monaco RTP System accepts patient diagnostic imaging data from CT and MR scans, and source dosimetry data, typically 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 then 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. Monaco RTP system then produces a display of radiation dose distribution within the patient, indicating not only doses to the target volume but to surrounding tissue and structures. The optimal plan satisfying the prescription is then selected, one that maximizes dose to the target volume while minimizing dose to surrounding healthy volumes.

The parameters of the plan are output for later reference and for inclusion in the patient file. Monaco planning methods and modalities:

- Intensity Modulated Radiation Treatment (IMRT) planning
- Electron, photon and proton treatment planning
- Planning for dynamic delivery methods (e.g. dMLC, dynamic conformal,
- Volumetric Modulated Arc Therapy (VMAT))

- Stereotactic planning and support of cone-based stereotactic
- 3D conformal planning
- Adaptive planning (e.g. for the Elekta Unity MR-Linac)
- Monaco basic systems tools, characteristics, and functions:
- Plan review tools
- Manual and automated contouring tools
- DICOM connectivity
- Windows operating system
- Simulation
- Support for a variety of beam modifiers (e.g. MLCs, blocks, etc.)
- Standardized uptake value (SUV)
- Specialty Image Creation (MIP, MinIP, and Avg)
- Monaco dose and Monitor Unit (MU) calculation:
- Dose calculation algorithms for electron, photon, proton planning

Monaco is programmed using C and C++ computer programming languages. Monaco runs on Windows operating system and off-the-shelf computer server/hardware.

V. 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, electron, and proton 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*

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Monaco RTP System version 6.2 is an updated version of the predicate device and has identical intended use and technological characteristics (identical designs, principles of operation, and use environments) as well as the same indications for use as the predicate device cleared per K213787.

The similarities and differences in key device characteristics and performance specifications of the current and predicate Monaco configuration are noted in the table below:
Through adequate verification, validation and usability evaluations, Elekta has concluded that the differences do not impact the substantial equivalence with the predicate device.

Technological Characteristics Comparison		Monaco (Subject Device)	Monaco (K213787)
Dose Calculation Algorithms	Monte Carlo – electron & photon (extended to include LET calculation for proton) Collapsed Cone (photon) Pencil Beam (optimization only) GPUMCD for MR-linac GPUMCD for proton Proton Pencil Beam	✓	✓
Proton Planning	Robustness optimization/evaluation, calculation using GPU based Monte Carlo & pencil beam algorithms and linear energy transfer (LET) evaluation capabilities will be available for Proton Arc Therapy planning.	✓	✓*
MR-Linac dose calculation	Calculates dose for MR-Linac dose calculation (including magnetic field, coils & cryostat)	✓	✓
Modality support	Supports IMRT, IGRT, particle therapy, stereotactic radiotherapy and MR-Linac treatments	✓	✓
Motion Management for MR-LINAC (Elekta Unity)	Adaptive Therapy with optional BLS (Baseline Shift) Recovery	✓	X
Beam Modelling	Beam modeling is performed by Elekta personnel. Standardized beam models are provided for some Elekta linac energy options. A new version of the Beam Modelling tool will be made available for users of Monaco 6.2 with a new GPUMCD dose calculator.	✓	✓
DICOM Connectivity	DICOM connectivity with compatible systems	✓	✓
Operating System	Windows operating system Support for Windows 10	✓	✓

*Same features made available to Proton Arc Therapy planning

VII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Design verification and performance testing were carried out in accordance with design controls of FDA's Quality System Regulation (21 CFR §820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 risk management requirements,IEC 62304 requirements for software life-cycle processes.

Non-clinical testing was performed to evaluate device performance and functionality against design and risk management requirements at sub-system, integration and system levels. Software verification testing was conducted and documented in accordance with FDA guidance[1] for devices that pose a major level of concern (Class C per IEC 62304).

Basic safety and essential performance have been satisfied through conformance with device-specific recognized consensus standards, as well as the general and collateral safety and essential performance standards for medical devices listed below.

[1] Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and Food and Drug Administration Staff, May 2005

Standard No.	Standard Title
ISO 14971	Medical Devices – Application of risk management to medical devices
IEC 62304	Medical device software – Software life-cycle processes
ISO 62083	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
IEC 61217	Radiotherapy equipment - Coordinates, movements and scales
IEC 62366-1	Medical devices - Application of usability engineering to medical devices
ISO 15223	Medical devices -Symbols to be used with medical devices, labeling and information to be supplied – Part 1: General requirements

VIII. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that Monaco is as safe and effective and performs as well as the predicate device.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

Monaco is substantially equivalent (SE) to the predicate device, Monaco (K213787). The intended use and indications for use are identical to the predicate device and the principles of operation remain unchanged.

The technological characteristics are substantially equivalent to the predicate device; the additional motion management strategies do not affect the fundamental scientific technology or raise different questions of safety or effectiveness of the device.
The device safety and performance have been addressed by non-clinical testing in conformance with pre-determined performance criteria, FDA guidance, and recognized consensus standards.

The results of verification and validation as well as conformance to relevant safety standards demonstrate that Monaco meets the established safety and performance criteria and is substantially equivalent to the predicate device.