May 17, 2022

Elekta Solutions AB
% Anju Kurian
Manager, Regulatory Affairs - Software
Kungstensgatan 18 Box 7593
Stockholm, Stockholms lan [SE-01] SE10393
SWEDEN

Re: K213787
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: April 18, 2022
Received: April 19, 2022

Dear Anju Kurian:

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,

Julie Sullivan, Ph.D.
Assistant Director
DHT 8C: 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)*
K213787

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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510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

Elekta Solutions AB
Kungstensgatan 18 Box 7593
Stockholm, Stockholms lan [SE-01] SE SE10393

Contact: Anju Kurian, M.S., RAC
Manager, Regulatory Affairs - Software

Establishment Registration #: 3015232217
510(k) Number: K213787
Date Prepared: 18 April 2022

II. DEVICE

Trade Name: Monaco RTP System
Release Version: Release 6.1
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

Monaco RTP System (K202789)

IV. 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

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The principles of operation of the proposed version of Monaco are the same as the currently cleared version of Monaco.

The major changes in this release are enhancements to the proton functionality that was cleared under predicate device K202789. These include proton robust optimization, proton robust evaluation and proton linear energy transfer (LET).

Robustness optimization and robust evaluation are extension to the cleared features in Monaco 6.0.

The ability to calculate LET is a calculation option for Monaco users using proton treatment plan modality and the Monte Carlo algorithm. The functionality is an extension of the existing Monte-Carlo algorithm with no change to the high-level clinical workflow and no impact to accuracy of dose calculation for Monaco users.

Some other non-significant changes are also included in this release.

VII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

Development, verification, and validation activities for the modified system were carried out in accordance with design controls as required by FDA's Quality System Regulation (21 CFR §820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 Risk Management requirements, and IEC 62304 requirements for software life-cycle processes. Non-clinical testing was performed to evaluate device performance and functionality in accordance with design and risk management requirements at subsystem, integration and system levels including interoperability.

Documentation of software development and verification testing activities for Monaco is maintained in accordance with FDA's "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,*" May 2005, for devices that pose a major level of concern (Class C per IEC 62304).

Formal validation of the clinical workflows has been performed on a clinically representative production equivalent system by competent and professionally qualified personnel. The following validation testing was conducted regarding the LET functionality introduced in Monaco 6.1:

a. The LET to water and medium were calculated for monoenergetic spots in Monaco and Geant4 for a range of energies and materials. The results were quantitatively compared to each other as well as qualitatively compared to other published results.
b. LET distributions for complex multiple spot and multiple beam arrangements as well as plan summations were calculated in Monaco and compared to expected values as obtained through manual summation of individual spots according to the design equations.

VIII. SUMMARY OF PERFORMACE TESTING (CLINICAL)

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

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

Monaco RTP System is substantially equivalent (SE) to the predicate device, Monaco RTP System (K202789). 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; enhancements to existing functionality 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 predetermined performance criteria, FDA guidance, and recognized consensus standards.

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