February 19, 2026

Elekta Solutions AB
Elinor Li
Sr. Regulatory Specialist
Hagaplan 4
Stockholm, 113 68
Sweden

Re: K252002
Trade/Device Name: Monaco RTP System (6.3)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: June 27, 2025
Received: June 27, 2025

Dear Elinor Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252002

Please provide the device trade name(s).

Monaco RTP System (6.3)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

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

Traditional 510(k) Summary (21 CFR § 807.92)

I. Submitter

Address	Elekta Solutions AB Hagaplan 4 113 68 Stockholm Sweden
Contact	Elinor Li Sr. Regulatory Specialist, Regulatory Affairs Software +1 (224) 6022203 / + 86 18817581406 Elinor.Li@elekta.com
510(k) Number	K252002
Date Prepared	2025-06-27

II. Device

Trade Name	Monaco RTP System (6.3)
Brand Name	Monaco, Elekta One | Planning, Elekta One | Planning Pro
Product Classification	Class II
Common Name	Monaco Radiotherapy Treatement Planning (RTP)
Classification Name	System, Planning, Radiation Therapy Treatment
Regulation Number	21 CFR 892.5050
Product Code	MUJ

III. Predicate Device

Predicate #	K223233
Predicate Trade Name	Monaco RTP System (6.2)
Predicate Product Code	MUJ

IV. Device Description Summary

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
- Distributed planning configurations (e.g.,for conventional linac)
- Adaptive planning capabilities (e.g.,for MR-Linac & conventional linac)
- Auto planning features (e.g.,for conventional linac)

Monaco basic systems tools, characteristics, and functions:

- Plan review tools
- Manual and automated contouring tools (Segmentation component for MR images)
- 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, 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. Intended Use/ Indications for Use Comparison

The Monaco Indication for Use Statement and Intended use remain unchanged from the Indications for Use Statement and intended use cleared under predicate device K223233.

VII Comparison to Predicate

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Item	Predicate Device	Subject Device	Substantial Equivalence Discussion
Indications	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 the	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	No change

	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	distributions inside the 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	
Use Environment	Access-controlled Healthcare facilities	Access-controlled Healthcare facilities	No change
Dose Calculation Algorithms	Monte Carlo - electron & photon Collapsed Cone (photon) Pencil Beam (only used when optimization) GPUMCD for photon (MR linac) GPUMCD for proton Proton Pencil Beam	Monte Carlo - electron & photon Collapsed Cone (photon) Pencil Beam (only used when optimization) GPUMCD for photon (both MR linac and conventional linac) GPUMCD for proton Proton Pencil Beam	Substantially Equivalent GPUMCD extends from MR linac to conventional linac.
Proton planning	Yes	Yes	No change
Dose calculation for MR-Linac (including magnetic field, coils & cryostat)	Yes	Yes	No change
Adaptive Therapy Planning	Adaptive therapy planning for MR linac	Adaptive therapy planning for MR linac & conventional linac	Substantially Equivalent Adaptive Therapy Planning functionalities are extended from MR linac (UNITY) to conventional Linac (EMLA). Enables offline adaptive planning on EMLA.
Auto Planning	No	Yes (for conventional linac)	Substantially Equivalent Auto planning feature for iterative modification of optimization cost function parameters introduced in subject device.
Contouring	Yes (with traditional algorithm)	Yes (with traditional and machine learning algorithm)	Substantially Equivalent The Segmentation Component utilizes machine-learning based models to automatically segment MR image sets introduced in subject device.

Distributed planning deployment	Yes (for conventional linac)	Yes (for conventional linac)	No change
Local Biological Measure Optimization	Hypertion Optimizer (Constrained Optimization)	Next Generation Optimizer (GPU-accelerated Hypertion Optimizer)	Substantially Equivalent Next Generation Optimizer in the subject device is the GPU based optimizer which uses Pseudo-Gradient Descent algorithm.
Operating System	Windows 10	Windows 10	No change
DICOM RT Support	Yes	Yes	No change
Programming Language	C, C++, C#	C, C++, C#	No change
Modalities Supported	Photon, Electron, Proton	Photon, Electron, Proton	No change
Beam modelling	Beam modeling is performed by Elekta personnel. Standardized beam models are provided for some Elekta linac energy options.	Beam modeling is performed by Elekta personnel. Standardized beam models are provided for some Elekta linac energy options.	No change
Scripting	UI based scripting	Both UI based and non-UI based scripting	Substantially Equivalent
Archive/ Retrieve	Yes	Yes	No change
Standards Compliance	ISO 13485 ISO 14971 IEC 62304 IEC 62083 IEC 82304-1 IEC 61217 IEC 62366-1 ISO 15223-1	ISO 13485 ISO 14971 IEC 62304 IEC 62083 IEC 82304-1 IEC 61217 IEC 62366-1 IEC 81001-5-1 ISO 15223-1 ISO 20417	Substantially Equivalent
Compatibility with Connected Systems	• EMLA • MR-linac Unity • MOSAIQ • Smart flow	• EMLA • MR-linac Unity • MOSAIQ • Third party contouring tools • Smart flow	Substantially Equivalent

VIII Technological Comparison

At a high level, both the predicate device and the subject device are based on the same characteristics:

Monaco RTP System version 6.3 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 K223233. Any difference in the technological characteristics do not raise new questions of safety and effectiveness as proven by established methods of verification and validation.

The new features introduced into the subject device are described below:

Monaco now provides, through software system modification,

- auto planning feature for iterative modification of optimization cost function parameters,

- segmentation component for invoking MR auto-segmentation algorithms,
- interoperability with 3rd party software for image management and contouring and
- extending the adaptive planning capabilities to EMLA for offline adaptive planning.

IX. Summary of Performance Testing (Non-Clinical)

Testing in the form of manual and automated verification were performed to evaluate the performance and functionality of the new features against requirement specification.

Regression test of unchanged functionalities in the subject device was done to ensure that new and updated functionalities did not introduce any undesirable effects.

Design validation of the device have been performed by competent and professionally qualified personnel to ensure that the product fulfils the intended use and user needs. The design validation also ensured that the risk control measures associated with functions related to safety for the affected functionality were effective.

The following testing was performed to establish substantial equivalence for the changes in scope of this 510(k):

Changes on scope of Monaco 6.3	Testing Performed to establish substantial equivalence
Segmentation component for invoking MR auto-segmentation algorithms	For the AI-based segmentation component, performance testing was conducted for the models – Female Pelvis Intact & Hysterectomy (trained on a joint image set of 529 images), Male Pelvis (trained on an image set of 250 images) and Head& Neck trained on an image set of 1862 images). The primary metric for evaluating the model's performance is the Average Hausdorff Distance (AVD). The acceptance threshold is set at 3 mm. A DICE or AUC value of 0.7 is also taken to represent a value of interest that might indicate model performance with respect to a structure or set of structures, however the DICE and AUC results were not explicitly used as the pass/fail metric. Quantitative performance evaluation demonstrated that, for all evaluated structures across all models, the mean Absolute Volume Difference (AVD) was less than 3 mm. Structure specific statistical analyses supported this conclusion. In addition, for all structures and models, the patterns of failure for any structure that did not meet the Dice Similarity Coefficient (DICE) confidence value of interest of 0.7 were investigated and any findings were included as "Limitations". Sub-group analysis is carried on the assessment of performance in the patient size, pixel size, slice spacing and number of slices subgroups. Additionally, qualitative analysis has also been executed based on a 5-point Likert scale with a conclusion that the automatically generated structures provided a valuable starting point for clinical delineation.
Auto-planning	Verification testing was performed to evaluate the Auto-Planning functionality, including workflow performance, protocol management, plan creation, interoperability, and error handling. Validation testing demonstrated that the Auto-Planning functionality supports the creation of clinically acceptable treatment plans for the intended use. Treatment plans generated using Auto-Planning were reviewed within the clinical workflow and determined to be suitable for clinical use, without introducing new safety or

	effectiveness concerns. All testing met pre-defined acceptance criteria.
Extending the adaptive planning capabilities to EMLA for offline adaptive planning	Verification testing was performed to evaluate the offline adaptive planning functionality using Monaco. Testing assessed correct system behavior during image registration, structure propagation, dose recalculation/re-optimization, offline adaptive plan generation, and workflow execution under representative clinical scenarios. The purpose of testing was to confirm that offline adaptive planning functions operate as intended and support the creation of an updated treatment plan based on CBCT imaging without compromising data integrity or workflow performance. No defects, unexpected behavior, or data integrity issues were identified during testing. Validation testing demonstrated that offline adaptive planning using CT-to-CBCT supports creation of clinically acceptable treatment plans for the intended use. The offline adaptive plans generated using CBCT imaging were reviewed within the clinical workflow and determined to be suitable for use. Verification and validation testing met pre-defined acceptance criteria.
Interoperability with 3rd party software for image management and contouring	The device incorporates or interfaces with third-party contouring functionality intended to support radiotherapy treatment planning. Verification and validation testing were conducted to confirm that the third-party contouring performs as intended and does not adversely impact the safety or effectiveness of the overall system. Verification testing was conducted to confirm correct DICOM export functionality, preservation of data integrity, and successful creation of an offline adaptive plan when using the third-party contouring functionality. Validation testing was conducted to verify the treatment planning workflows in a Treatment Planning System (TPS) and treatment preparation in Record and Verify (R&V) system. Acceptance criteria were defined to ensure that third-party contouring outputs are clinically acceptable and comparable to reference contours produced by qualified users. All verification and validation testing met the predefined acceptance criteria. All planned Solution Interoperability test cases have been successfully executed and passed.

Results from verification and validation testing demonstrate that conformance to applicable technical requirement specification and user needs have been met and that the device functions as intended.

X. Summary of Performance Testing (Clinical)

No animal or clinical tests were performed to establish substantial equivalence with the predicate device. The performance data demonstrate that the subject device is as safe and effective and performs as well as the predicate devices (K223233).

XI. Substantial Equivalence Conclusion

The subject device, Monaco 6.3 is substantially equivalent (SE) to the predicate Monaco 6.2 (K223233). 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 device safety and performance have been established by non-clinical testing in conformance with predetermined performance criteria, FDA guidance, and recognized consensus standards.

The result of verification and validation as well as conformance to relevant safety standards demonstrate that Monaco 6.3 meets the established safety and performance criteria and is substantially equivalent to the predicate device.