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: K223229
Trade/Device Name: MOSAIQ® Oncology Information System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
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 14:33:58 -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)*

K223229

Device Name

MOSAIQ® Oncology Information System

Indications for Use *(Describe)*

MOSAIQ® is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed. Users can configure MOSAIQ® for Medical Oncology use, Radiation Oncology use, or the two together. Medical oncology dose calculations are designed to support both adult and pediatric patients.
It lets users:
• Assemble electronic patient charts and treatment plans, order diagnostic tests, and prescribe medications.
• Generate and keep medication formulary lists and calculate applicable medication dosages for medical oncology.
• Import, view, annotate, adjust, enhance, manage and archive images.
• Compare radiation treatment plans and evaluate dose coverage.
• Design leaf plans for operation with radiotherapy treatment machines that have multi-leaf collimators.
• Make sure radiation treatment plans imported from treatment planning systems agree with treatment machine constraints. MOSAIQ® reads actual settings from the treatment machine through the machine communication interface. It compares these settings with predefined values. If a mismatch occurs between the planned values and the actual machine settings, the system warns the user.
• View reference images to setup treatment. MOSAIQ® refers to predefined settings to help treatment machine setup and communicates patient and machine setup instructions.
• Record actual delivered radiation values in an electronic chart to track treatment.
• Use stereotactic localization to calculate set-up coordinates for treatments.
• Monitor Intrafractional motion with real time image overlay.

MOSAIQ® is not intended for use in diagnosis.

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."

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: K223229

Date Prepared: 7 December 2022

II. DEVICE

Trade Name: MOSAIQ Oncology Information System

Product Classification: Class II

Common Name: Radiation charged-particle radiation system

Regulation Number: 21 CFR § 892.5050

Regulation Description: Medical charged-particle radiation therapy system

Product Code: IYE

III. PREDICATE DEVICE

Predicate Device: MOSAIQ OIS (K203172)

IV. DEVICE DESCRIPTION

The MOSAIQ® Oncology Information System (OIS) is an image-enabled electronic medical record system. It manages clinical and administrative workflows within oncology departments and facilitates efficient patient care. It can be configured for Medical Oncology, Radiation Oncology, or both.

The Medical Oncology (MO) configuration is a medical oncology charting solution that includes customizable regimens (Care Plans) that automate chemotherapy orders for labs, procedures, and appointments. Configurable flowsheet views are used for reviewing treatment administration, documents, assessment and lab data. Users can enter medications and screen for drug/drug and drug/allergy interactions. MOSAIQ also performs standard calculations such as Body Surface Area (BSA) and Area Under the Curve (AUC). The Medical Administration Record (MAR) supports all information related to chemotherapy and blood product administration, clinical trial study drugs, dose amounts, infusion time, multiple administration, etc.

The Radiation Oncology configuration is also a charting solution with Computerized Physician Order Entry (CPOE) capability, along with added features for image management, patient setup and positioning, verify and record, plan import, review, and approval, stereotactic localization, and pretreatment checks. MOSAIQ's Radiation Oncology functionality can be used to support a wide variety of treatment modalities including Intensity Modulated Radio Therapy (IMRT), Image Guided Radio Therapy (IGRT), particle therapy, and stereotactic radiotherapy. It can import and store treatment plans from Therapy Planning Systems (TPS) via DICOM import/DICOM RT import.

In addition to these, the current version of MOSAIQ introduces the following modifications for radiation oncology:

- Anatomic Position Monitoring (APM) with Manual interrupt (also referred to as True Tracking as it 'tracks' in 3D and enables the system to gate using the 3D position of the anatomy's motion)
- APM with Anatomic Tolerance Check (ATC)
- Adaptive Therapy with optional Baseline Shift (BLS) Recovery
- Care Rules for motion management.

These modifications are not contained solely within MOSAIQ, as the full clinical benefit is achieved with interoperability of Unity, Monaco RTP, and MOSAIQ OIS.

V. INTENDED USE / INDICATIONS FOR USE

MOSAIQ® is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed. Users can configure MOSAIQ® for Medical Oncology use, Radiation Oncology use, or the two together. Medical oncology dose calculations are designed to support both adult and pediatric patients. It lets users:

- *Assemble electronic patient charts and treatment plans, order diagnostic tests, and prescribe medications.*
- *Generate and keep medication formulary lists and calculate applicable medication dosages for medical oncology.*
- *Import, view, annotate, adjust, enhance, manage and archive images.*
- *Compare radiation treatment plans and evaluate dose coverage.*
- *Design leaf plans for operation with radiotherapy treatment machines that have multileaf collimators.*
- *Make sure radiation treatment plans imported from treatment planning systems agree with treatment machine constraints.*

MOSAIQ® reads actual settings from the treatment machine through the machine communication interface. It compares these settings with predefined values. If a mismatch occurs between the planned values and the actual machine settings, the system warns the user.

- *View reference images to setup treatment. MOSAIQ® refers to predefined settings to help treatment machine setup, and communicates patient and machine setup instructions.*
- *Record actual delivered radiation values in an electronic chart to track treatment.*
- *Use stereotacticlocalization to calculate set-up coordinates for treatments.*
- *Monitor intrafractional motion with real time image overlay.*

MOSAIQ is not intended for use in diagnosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE

MOSAIQ® Oncology Information System version 3.2 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 K203172.

The similarities and differences in key device characteristics and performance specifications of the current and predicate MOSAIQ 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		MOSAIQ (Subject Device)	MOSAIQ (K203172)
Administrative Features – MDDS (non-medical) Features	Practice management features – billing, scheduling, scheduling, billing, management reporting and data analysis	✓	✓
Medical oncology management	Includes plan of care management, calculation of medication dosage, and dose delivery tracking	✓	✓
Radiation Oncology Management	Ability to add a radiation prescription, import radiation therapy treatment plans, machine setup including patient positioning, treatment calendar management, cumulative dose tracking and eChart Check feature for weekly chart check. Review of treatment plans through Evaluate feature.	✓	✓
Imaging Functionality	Ability to import, view, annotate, manipulate, enhance, manage and archive images	✓	✓
Record and Verify-Sequencer	Verifies radiation treatment plans against treatment machine constraints, provides the capability to notify clinicians of actions that need to take place prior to treatment, displays reference images for setup purposes, and facilitates treatment machine setup according to predefined settings. Recording of actual treatment values and interfaces with treatment machines.	✓	✓
MLC Fit	Design leaf plans for operation with radiotherapy treatment machines that have multi-leaf collimators.	✓	✓
Modality support	Supports IMRT, IGRT, particle therapy, stereotactic radiotherapy and MR-Linac treatments	✓	✓
Motion Management in Treatment Session Manager	Motion monitoring with manual interrupt	✓	✓
	Anatomical Position Monitoring (APM) with manual interrupt	✓	X
	APM with ATC (Anatomical Tolerance Check)	✓	X
	Adaptive Therapy with optional BLS (Baseline Shift) Recovery	✓	X
Stereotactic Localization	Stereotactic localization through MOSAIQ LOCATE feature allows clinicians to visualize the target on patient images, perform image calibration, and calculate stereotactic coordinates.	✓	✓
DICOM Connectivity	DICOM connectivity with compatible systems	✓	✓
Operating System	Windows operating system Support for Windows 10	✓	✓

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.

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 62274	Medical electrical equipment – Safety of radiotherapy record and verify systems
AAMI RT2:2017	Radiation therapy readiness check
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 MOSAIQ is as safe and effective and performs as well as the predicate device.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

MOSAIQ is substantially equivalent (SE) to the predicate device, MOSAIQ (K203172). 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 MOSAIQ meets the established safety and performance criteria and is substantially equivalent to the predicate device.

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