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

December 18, 2020

Re: K203172
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: October 20, 2020
Received: October 26, 2020

Dear Ms. 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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K203172

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. 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.

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

I. SUBMITTER

	Elekta Solutions AB Kungstensgatan 18 Box 7593 Stockholm, Stockholms lan [SE-01] SE SE10393
Contact:	Melinda Smith, MS, RAC, CBA Melinda.Smith@elekta.com
Establishment Registration Number:	3015232217
510(k) Number:	K203172
Date Prepared:	20 October 2020

II. DEVICE

Trade Name:	MOSAIQ® Oncology Information System
Release Version #:	Release 3.00
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

MOSAIQ® Oncology Information System (Release version 2.65)
510(K) Number: K183034

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 sites

of administration, etc. MOSAIQ's Medical Oncology functions are designed for adult patient care. It is labeled accordingly and calculates all doses accordingly.

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.

LEVEL OF CONCERN

Guidance for Industry and FDA Staff - *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005) Table 1, item 4b states, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?" The record and verify function within MOSAIQ does not directly control the linear accelerator that delivers the radiation; however, it does interface with the linear accelerator and is responsible for detecting potential mismatches between planned and actual machine settings and alerting the user. Therefore, it is a major level of concern function.

DEVICE CHANGES WITHIN SCOPE OF THIS 510(k)

- The intended patient population for MOSAIQ's Dose Calculation functions has been expanded to include patients under the age of 18 years.
- The Patient Setup Workspace (PSW) enhances upon the previous functionality within MOSAIQ by introducing improved and simplified workflows for imaging and treatment delivery associated with the daily setup of patients. The simplified User Interface (UI) and workflow minimizes navigating through multiple systems adding a seamless workflow for the user. It also compliments hardware changes introducing better integration and streamlining processes.
- 2D Image Review Application (2D IRA) enhances the image review workflow of imported 2D images from associated X-ray Volume Imaging (XVI) systems allowing images to be reviewed against the treatment plan providing a more user-friendly interface.
- Plan of Care supports imaging workflow automation rules assignment, aiding efficient and consistent action on offset analysis and 2D image registration tasks assigned to a patient (i.e. Image Plan).
- MOSAIQ Data Director is now incorporated as a component within the MOSAIQ software.

V. 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. It lets users:

- Assemble electronic patient charts and treatment plans, order diagnostic tests, and prescribe medications.
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- 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

MOSAIQ® Oncology Information System version 3.00 is an updated version of the predicated 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 (with expanded patient population to include pediatrics for medical oncology dose calculation functions) as the predicate device cleared per K183034.

Technological Characteristics Comparison	MOSAIQ (Subject Device)	MOSAIQ (K183034)
Comparison of multiple radiation treatment plans	✓	✓
Radiation treatment plan summation and subtraction	✓	✓
Includes ability to evaluate brachytherapy & external beam radiation treatment plans	✓	✓
Isodose & beam display	✓	✓

Supports frame-based stereotactic localization	✓	✓
Contouring, optimization and radiation dose calculation.	X	X
Support for IMRT	✓	✓
Support for IGRT	✓	✓
Support for adaptive therapy	✓	✓
Patient positioning using volumetric images	✓	✓
Motion management within the MR-Linac environment includes continuous stream of MR images during treatment, refreshing multiple times per second.	✓	✓
Motion management within the MR-Linac environment includes automatic gating in response to patient motion	X	X
Integrated software & treatment delivery hardware: Radiation software for image guidance and linear accelerator to deliver radiation therapy	MOSAIQ is a separate, standalone software device	
Security features to enable customer HIPAA compliance	✓	✓
DICOM connectivity with compatible systems	✓	✓
Software runs on Windows operating system	✓	✓

VII. PERFORMACE DATA (NON-CLINICAL)

MOSAIQ has been developed in a manner consistent with accepted standards for software development and evaluated in accordance with design specifications and applicable safety and performance standards through software verification and validation.

Verification and Validation testing was performed ensure that the system is working as designed. A significant number of 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. MOSAIQ passed testing and was deemed safe and effective for its intended use and well as meeting identified user needs.

VIII. CONCLUSIONS

The subject device and predicate device have the same intended use with the exclusion of the expansion of scope to include pediatrics and the same technological characteristics. As demonstrated throughout the rest of this submission the subject and predicate device are substantially equivalent with minor differences and improvements in workflows for the subject device. These minor differences do not raise any new or escalated questions of safety or effectiveness of the device; therefore, Elekta's MOSAIQ® Oncology Information System (subject device) is substantially equivalent to Elekta's MOSAIQ® Oncology Information System (predicate device) cleared per K183034.