



Elekta, Inc
% Ms. Faiza Ahmed
Regulatory Affairs Specialist
100 Mathilda Place 5th Floor
SUNNYVALE CA 94086 US

December 4, 2018

Re: K183034

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 30, 2018
Received: November 1, 2018

Dear Ms. Ahmed:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent blue "FDA" logo.

Robert A. Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183034

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 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 stereotactic localization to calculate set-up coordinates for treatments.
- Observation of Intrafractional motion with real time image overlay.

MOSAIQ® is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.

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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October 30, 2018

MOSAIQ Oncology Information System Premarket Notification (510(k)) Summary of Safety and Effectiveness

INTRODUCTION

This document summarizes the safety and effectiveness information contained within the MOSAIQ Oncology Information System 510(k). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution.

PREMARKET NOTIFICATION INFORMATION

1. Product Information:
 - a. Product Trade Name MOSAIQ
 - b. Release Version Number Release 2.65
2. Classification Information:
 - a. Classification Name Medical charged-particle radiation therapy system
 - b. Common/Usual Name Radiation Treatment Planning System
 - c. Product Classification Class II
 - d. Product Code IYE
 - e. Reference 21 CFR 892.5050
 - f. Review Panel Radiology

3. Establishment Information:

- | | |
|-------------------------|--|
| a. Submitter | Elekta, Inc. |
| b. Submitter Address | 100 Mathilda Place 5 th Floor
Sunnyvale CA 94086 |
| c. Establishment Number | 2950347 |
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PREDICATE DEVICE INFORMATION

The MOSAIQ Oncology Information System is substantially equivalent to the following device that the Food and Drug Administration (FDA) has cleared for distribution and is currently being actively marketed in the United States. MOSAIQ is substantially equivalent to the following product in intended use and safety and effectiveness.

MOSAIQ Oncology Information System
IMPAC Medical Systems, Inc.
K141572

REFERENCE DEVICE INFORMATION

The MOSAIQ Oncology Information is using the following device as a reference device to demonstrate intended use and technical similarities. The Food and Drug Administration (FDA) has cleared the reference device for distribution and is currently being actively marketed in the United States.

The ViewRay (MRIdian) Linac System
ViewRay Incorporated

K162393

MOSAIQ 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. 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 stereotactic localization to calculate set-up coordinates for treatments.
- Observation of Intrafractional motion with real time image overlay.

MOSAIQ® is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.

OVERVIEW OF MOSAIQ

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 IMRT, IGRT, particle therapy, and stereotactic radiotherapy. It can import and store treatment plans from TPS systems via DICOM import/DICOM RT import.

LEVEL OF CONCERN

Item 4b of Table 1 in the FDA Guidance document entitled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices asks, "Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems..." The record and verify function within MOSAIQ does not directly control the machine 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. A failure in MOSAIQ can result in serious injury or even death can result, thus, we believe it is a major level of concern.

SUMMARY OF CLINICAL TESTING

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. Validation testing involved simulated clinical workflows, described in detail in section 16.8. The product was deemed fit for clinical use.

SUMMARY OF NON-CLINICAL TESTING

Verification tests were written and executed to 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.

Substantial Equivalence to Legally Marketed Products	MOSAIQ with new features	Predicate Device MOSAIQ (K141572)	Reference Device The ViewRay (MRIdian) Linac System (K162393)
Intended Use Comparison			
Ability to define leaf plans for use with radiotherapy treatment machines equipped with multileaf collimator	Yes	Yes	Yes
Ability to import, view, annotate, manipulate, enhance, manage and archive images	Yes	Yes	Yes
Allows users to create, view, and edit geometric information associated with treatment field definitions, including the MLC accessory.	Yes	Yes	Yes
Checks 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.	Yes	Yes	Yes
Verification against imported radiation treatment plans	Yes	Yes	Yes
Recording of actual delivered treatment values	Yes	Yes	Yes
Record-only interfaces for appropriate treatment machines	Yes	Yes	N/A – not a standalone V&R system
Integrated electronic patient charting functionality	Yes	Yes	N/A – not a standalone charting system
Administrative functions for practice management (e.g., scheduling, billing)	Yes	Yes	No
Medical oncology management including care plans, calculation of medication dosage & dose delivery tracking	Yes	Yes	No
Dose Volume Histogram (DVH) Statistics creation and display	Yes	Yes	Yes
Intrafractional motion with real time image overlay	Yes	No	Yes
Technological Characteristics Comparison			
Comparison of multiple radiation treatment plans	Yes	Yes	Yes
Radiation treatment plan summation and subtraction	Yes	Yes	Yes
Includes ability to evaluate brachytherapy & external beam radiation treatment plans	Yes	Yes	No

Isodose & beam display	Yes	Yes	Yes
Supports frame-based stereotactic localization	Yes	Yes	No
Contouring, optimization and dose calculation.	No	No	Yes
Support for IMRT	Yes	Yes	Yes
Support for IGRT	Yes	Yes	Yes
Support for adaptive therapy	Yes	No	Yes
Patient positioning using volumetric images	Yes	Yes	Yes
Motion management within the MR-Linac environment includes continuous stream of MR images during treatment, refreshing multiple times per second.	Yes	No	Yes
Motion management within the MR-Linac environment includes automatic gating in response to patient motion	No	No	Yes
Integrated software & treatment delivery hardware: Radiation software for image guidance and linear accelerator to deliver radiation therapy	MOSAIQ is a separate, standalone software device, with image guidance function designed for use with the MR Linac and tested accordingly.	N/A	K162393 addresses both treatment hardware and software.
Security features to enable customer HIPAA compliance	Yes	Yes	Yes
DICOM connectivity with compatible systems	Yes	Yes	Yes
Software runs on Windows operating system	Yes	Yes	Yes