January 6, 2012

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 2.40
2. Classification Information:	
a. Classification Name	Medical charged-particle radiation therapy system
b. Common/Usual Name	Oncology Information 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	IMPAC Medical Systems, Inc.
b. Submitter Address	100 Mathilda Place, 5th Floor Sunnyvale, CA 94086
c. Establishment Number	2950347
d. Contact	Kathryn Stinson, RA Specialist
e. Contact Phone	314-993-0003
f. Contact Fax	314-993-1175

PREDICATE DEVICE INFORMATION

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

1. ViewStation
   IMPAC Medical Systems, Inc.
   K043412

2. SEQUENCER
   IMPAC Medical Systems, Inc.
   K981313

3. MLC Fit
   IMPAC Medical Systems, Inc.
   K991133

4. ARIA Radiation Oncology
   Varian Medical Systems
   K093527

MOSAIQ INTENDED USE

MOSAIQ is an image-enabled electronic medical record system (EMR) used for oncology workflow management. It lets users:

- Supply electronic patient charts and assemble care plans, order diagnostic tests, and prescribe medications.
- Import, view, annotate, manipulate, enhance, manage, and archive images.
- Import, keep, and export information related to patient treatments to monitor treatment progress from a central location. This includes orders, documents, lab information, and other related information from compatible programs.
- Generate and keep medication and formulary lists and calculate applicable medication dosages for medical oncology.
- Design leaf plans for operation with radiotherapy treatment machines that have multileaf collimators. Users can give, view and change geometric data related to treatment fields, including the MLC accessory.

- Ensure plans imported from treatment planning systems agree with treatment machine constraints.

Additionally, MOSAIQ:

- Supplies other administrative functionality necessary to operate medical and radiation oncology departments.
- Shows reference images for setup purposes, refers to predefined settings to help treatment machine setup, and tells clinicians of necessary steps before treatment.
- Reads actual settings from the treatment machine through the machine's communication interface. It compares these settings with predefined values. If a mismatch occurs between the planned values and the actual machine settings, the system inhibits treatment.
- Verifies the actual treatment against radiation treatment plans. At applicable points during the treatment, it records the actual delivered values to provide treatment tracking.

MOSAIQ INDICATIONS FOR USE

MOSAIQ supports information flow among healthcare facility personnel. It can be used wherever radiotherapy and/or chemotherapy are prescribed. MOSAIQ is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.

DESCRIPTION OF THE PRODUCT

MOSAIQ is a multi-functional, integrated software suite that forms a comprehensive electronic oncology management system for medical and radiation oncology facilities. For both medical and radiation oncology users, MOSAIQ provides image-enabled electronic patient charting and record management as well as medical transcription and billing functionality. For radiation oncology users, it also includes the ability to import and export radiation treatment plan information, the ability to plan multileaf collimator (MLC) shapes, and verify and record treatment setup and delivery.

Previously, three of the components within MOSAIQ were cleared through the 510(k) process individually. The ViewStation software (K011694) provides the ability to to import, view, annotate, manipulate, enhance, manage and archive medical images and includes patient positioning functionality. The MLC Fit software (K991133) allows users to define MLC leaf shapes for radiation treatment plans. The SEQUENCER software (K981313) connects to the treatment unit (e.g. linear accelerator) and compares its setup

to the predefined treatment field in the treatment chart. SEQUENCER inhibits treatment if errors are detected, records actual treatment unit parameters, and allows this information to be stored and/or printed as part of the treatment record.

MOSAIQ includes the ViewStation, MLC Fit and SEQUENCER software applications as well as other applications that were not classified as medical devices when considered as individual products. This section of the Premarket Notification provides a description of the functional units within MOSAIQ.

LEVEL OF CONCERN

Because MOSAIQ includes many different pieces of functionality, we conclude that the level of concern for the device as a whole must be equivalent to that of the function with the highest level of concern, namely, the verify and record functionality.

The FDA guidance document entitled "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...."

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. Thus, it is a major level of concern function.

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. Bench testing was performed, as described in Section 16.8, using simulated clinical workflows and ad hoc testing where appropriate, with actual patient data. The product was deemed fit for clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathryn Stinson
Regulatory Affairs Specialist
IMPAC Medical Systems, Inc.
100 Mathilda Place, 5th Floor
SUNNYVALE CA 94086-6076

FEB 28 2012

Re: K120067
Trade/Device Name: MOSAIQ Oncology Information System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 6, 2012
Received: January 9, 2012

Dear Ms. Stinson:

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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120067

Device Name: MOSAIQ Oncology Information System

Indications for Use:

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Prescription Use _X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120067