MIM Software Inc.
% Ms. Lynn Hanigan
Quality Assurance Director
25800 Science Park Drive - Suite 180
CLEVELAND OH 44122

June 22, 2018

Re: K180815
Trade/Device Name: MIM - SPECTRA Quant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 7, 2018
Received: June 8, 2018

Dear Ms. Hanigan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180815

Device Name

MIM - SPECTRA Quant

Indications for Use *(Describe)*

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to,
CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

- Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.

- Create, display and print reports from medical images.

- Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.

- Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.

- Localization and definition of objects such as tumors and normal tissues in medical images.

- Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

- Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.

- Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).

- Post-treatment dose calculation and evaluation of permanent Yttrium-90 (Y90) microsphere implants.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images.
The software is not to be used for mammography CAD.

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.

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510(k) Summary of Safety and Effectiveness
(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25800 Science Park Drive – Suite 180
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: 6/7/2018

Device Name

Trade Name: MIM – *SPECTRA Quant*
Common Name: Medical Imaging Software
Regulation Number / Product Code: 21 CFR 892.2050 Product Code LLZ
Classification Name: System, Imaging Processing, Radiological

Predicate Devices

K172218	MIM – Y90 Dosimetry	MIM Software Inc.
K023190	E.CAM Computer / e.soft Workstation	Siemens
K162483	Symbia Intevo Bold (xSPECT Quantification)	Siemens

Intended Use

MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists.

MIM is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.

MIM provides the user with the means to display, register and fuse medical images from multiple modalities. Additionally, it evaluates cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.

The Region of Interest (ROI) feature reduces the time necessary for the user to define objects in medical image volumes by providing an initial definition of object contours. The objects include, but are not limited to, tumors and normal tissues.

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MIM provides tools to quickly create, transform, and modify contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems and archiving contours for patient follow-up and management.

MIM aids in the assessment of PET/SPECT brain scans. It provides automated quantitative and statistical analysis by automatically registering PET/SPECT brain scans to a standard template and comparing intensity values to a reference database or to other PET/SPECT scans on a voxel by voxel basis, within stereotactic surface projections or standardized regions of interest.

MIM allows the dose distribution of an implant to be individually shaped for each patient and is a general purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using permanent implants of various radioisotopes.

For Yttrium-90 (Y90) microspheres, MIM should only be used for the retrospective determination of dose and should not be used to prospectively calculate dose for the case where there is a need for retreatment using Y90 microspheres.

Indications for Use

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

- Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.
- Create, display and print reports from medical images.
- Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.
- Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.
- Localization and definition of objects such as tumors and normal tissues in medical images.
- Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.
- Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.
- Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).
- Post-treatment dose calculation and evaluation of permanent Yttrium-90 (Y90) microsphere implants.

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Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.

Device Description

MIM – *SPECTRA Quant* is a feature of MIM. It is designed for use in medical imaging and operates on both Windows and Mac computer systems. MIM – *SPECTRA Quant* extends the functionality MIM – Y90 Dosimetry (K172218) software. The following functions have been added to allow quantitative reconstructions of Single Photon Emission Computed Tomography (SPECT) scans:

- Allows for decay correction of activity back to time of injection
- Allows for correction of photon attenuation
- Allows for correction of photon scatter
- Allows for correction of collimator detector resolution effects
- Allows for camera sensitivity calibration providing output in Becquerels per ml (Bq/ml)

Substantial Equivalence

MIM – *SPECTRA Quant* is substantially equivalent to a combination of the predicate devices MIM – Y90 Dosimetry (K172218), Siemens - E.CAM Computer / e.soft Workstation (K023190), and Siemens - Symbia Intevo Bold (xSPECT Quantification) (K162483).

Performance Data

Validation testing with MIM – *SPECTRA Quant* was performed by board certified clinicians. In all cases, the software passed its performance requirements and met specifications. Additionally, clinicians using MIM – *SPECTRA Quant* performed validation in comparison to independently implemented, industry-standard solutions. It was demonstrated that MIM software, when used according to operating instructions, can be used safely and effectively.

Furthermore, MIM Software Inc. has conducted performance and integration testing on MIM – *SPECTRA Quant* software. Standard quality control phantoms, a Liver phantom, and simulated phantoms based on the NEMA IEC Body Phantom were used for verification testing. All tests were performed using standard clinical acquisition and reconstruction protocols.

The accuracy of corrections for attenuation, scatter, and resolution effects were verified in physical and simulated phantoms as well as with clinical data. In all cases, the software passed its performance requirements and met specifications. All reconstructions of clinical data were rated as acceptable for clinical use by the qualified Nuclear Medicine professionals.

The absolute quantitative accuracy of MIM – *SPECTRA Quant* was verified in physical and simulated phantoms for various isotope-collimator combinations. The acceptance criterion for MIM – *SPECTRA Quant* is a quantitative error of smaller or equal to 10% in regions that are large enough not to be affected by the partial volume effect. The error in reconstructed activity concentration for these regions was less than 5% which was better than the predefined requirements. In small targets the

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partial volume effect lowers the accuracy as expected and was similar to the accuracy of the predicate device for these regions.

Quantitative Accuracy Verification of MIM – *SPECTRA Quant*

Isotope	Collimator	Acceptance Criteria*	Quantitative Error	Verification Result
Tc99m	LEHR	<10%	<5%	Passed
I-123	LEHR	<10%	<5%	Passed
I-131	HE	<10%	<5%	Passed
Lu-177	ME	<10%	<5%	Passed

*Acceptance criteria was <10% error in regions that are large enough not to be affected by partial volume effect.

The testing for half-time or half-dose imaging demonstrated that OSEM with corrections for attenuation, scatter, and resolution met the requirements of similar or superior image quality metrics compared to a full-time or full-dose FBP reconstruction.

In conclusion, MIM Software Inc. has conducted performance testing on the MIM – *SPECTRA Quant* software. In all cases, the software passed its performance requirements and met specifications.