MultiModal Imaging Services Corporation (dba HealthLytix)
% Stephen Kosnosky, PMP, ASQ CMQ/OE
Quality and Regulatory Manager
4747 Executive Drive, Suite 820
SAN DIEGO CA 92121

November 19, 2019

Re: K191278
Trade/Device Name: RSI-MRI+
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 8, 2019
Received: November 12, 2019

Dear Mr. Kosnosky:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191278

Device Name
RSI-MRI+

Indications for Use *(Describe)*

RSI-MRI+ is indicated for use as automatic post-acquisition image processing software for analysis of diffusion-weighted and anatomical magnetic resonance imaging data.

RSI-MRI+ is intended for automatic fusion of derived diffusion-weighted MRI data with anatomical T2-weighted MR images.

RSI-MRI+ is additionally intended to provide automatic prostate segmentation, quantification, and reporting of derived image metrics.

RSI-MRI+ is not intended for use in pediatric populations.

RSI-MRI+ is not intended to diagnose, treat, or prevent diseases or conditions.

RSI-MRI+ is intended to be used in a variety of settings such as hospitals, clinics, and medical offices.

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 K191278

Submission Information:

Submitter's Name	MultiModal Imaging Services Corporation (dba HealthLytix)
Submitter's Address	4747 Executive Drive, Suite 820 San Diego, CA 92121
Submitter Telephone	+001.619.340.0503
Contact Name	Stephen Kosnosky PMP, ASQ CMQ/OE
Date Prepared	Sept 18, 2019
Trade or Proprietary Name	RSI-MRI+
Common or Usual Name	Picture Archiving and Communications System
Classification Name	System, Image Processing, Radiological) (21 CFR 892.2050)
Regulatory Class	Class II
Product Code	LLZ
Predicate Device	Eigen ProFuse CAD (K173744) As of submission date this predicate device has not been subject to a design-related recall. No reference devices were used in this submission.

Device Description:

RSI-MRI+ is standalone software that is used by radiologists, urologists, and other clinicians to assist with analysis and interpretation of medical images. RSI-MRI+ accepts DICOM images using supported protocols and performs automatic post-acquisition analysis of diffusion-weighted magnetic resonance imaging (DWI) data and optional automated fusion of derived image data with anatomical T2-weighted MR images.

Some of the features of RSI-MRI+ include:

- **Restricted Signal Map:** The derived image data produced by RSI-MRI+ includes an enhanced DWI map (the *Restricted Signal Map*), which demonstrates improved conspicuity of restricted diffusion compared to standard DWI maps.
- **Color Fusion Series:** RSI-MRI+ can be configured to produce a color fusion series which overlays the *Restricted Signal Map* intensity onto the anatomical T2-weighted image series.
- **Automated Prostate Segmentation:** RSI-MRI+ uses artificial intelligence (AI) powered by a deep learning algorithm to automatically segment the prostate on anatomical T2-weighted images. The segmentation result is provided in the separate *Prostate Segmentation Series*.
- **Automated Segmentation Report:** RSI-MRI+ generates a report of segmentation volume and images of the segmented prostate as a colored outline on the anatomical image.
- **Export:** RSI-MRI+ outputs are provided in standard DICOM format, which is compatible with most third-party commercial PACS workstation software.

NOTE: The RSI-MRI+ supported protocols differ from PI-RADS v2.1 in that they have lower in-plane resolution for T2W images and thicker slices for the GE DWI.

Indications for Use:

RSI-MRI+ is indicated for use as automatic post-acquisition image processing software for analysis of diffusion-weighted and anatomical magnetic resonance imaging data.

RSI-MRI+ is intended for automatic fusion of derived diffusion-weighted MRI data with anatomical T2-weighted MR images.

RSI-MRI+ is additionally intended to provide automatic prostate segmentation, quantification, and reporting of derived image metrics.

RSI-MRI+ is not intended for use in pediatric populations.

RSI-MRI+ is not intended to diagnose, treat, or prevent diseases or conditions.

RSI-MRI+ is intended to be used in a variety of settings such as hospitals, clinics, and medical offices.

Substantial Equivalence:

The product's technical features are substantially equivalent to the ProFuse CAD (K173744). Many of the features of the ProFuse CAD (K173744) software are included in RSI-MRI+. RSI-MRI+ is standalone software that runs on a network connected server or PC workstation. The RSI-MRI+ device accepts DICOM image data as input to perform image processing including diffusion series analysis, automatic segmentation, fusion of images, and automated reporting from MRI scans.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Software devices
- DICOM compatibility for input and output
- Diffusion-series analysis
- Image fusion
- Automated reporting
- MRI Image analysis
- Display and measurement data may be viewed, accepted, or rejected by a clinician
- For use in hospital, clinic, or medical office

The following differences exist between the subject and predicate devices:

- Image format compatibility (RSI-MRI+ is compatible with DWI-MRI, predicate has additional compatibility with MRI, CT, PET)
- Contrast image processing (RSI-MRI+ does not contain this functionality)
- Co-registration (RSI-MRI+ does not contain this functionality)
- Image annotation (RSI-MRI+ does not contain this functionality)
- Manual segmentation (RSI-MRI+ has automatic segmentation, predicate uses manual segmentation)
- Image viewing (RSI-MRI+ does not contain this functionality, images are viewable on most 3rd party commercial PACS workstation software)

Predicate Device:

Function	RSI-MRI+ (Subject Device)	ProFuse CAD (K173744)
Product Code	LLZ	LLZ
DICOM Input	DICOM compatible	DICOM compatible
Diffusion – series analysis	Post-processing analysis of Diffusion MRI data with multi-compartment RSI model.	Post-processing analysis of Diffusion MRI data with single compartment DWI model.
Segmentation	Automated Prostate Segmentation: RSI-MRI+ software provides automatic prostate segmentation, quantification, and reporting of derived image metrics.	Manual Prostate Segmentation: ProFuse CAD has a marking feature that allows the user to manually segment the prostate and provides quantification and reporting of derived image metrics.
Co-Registration	Does not contain this functionality.	Performs co-registration of images.
Fusion	Automated fusion of derived Diffusion MRI data with anatomical MRI data	Automated fusion of derived Diffusion MRI data with anatomical MRI data in addition to other data sources
Report	Yes	Yes
DICOM output	DICOM compatible	DICOM compatible
Data Source	MRI Scanner	MRI Scanner, CT Scanner, PET Scanner
Safety	Display/measurement data can be viewed, accepted, or rejected by a physician.	Display/measurement data can be viewed, accepted, or rejected by a physician.
Environment for use	Hospital, Clinic, Medical Office	Hospital, Clinic, Medical Office, Home Office

Testing and Performance Data:

The following performance data were provided in support of the substantial equivalence determination:

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket

Submissions for Software Contained in Medical Devices". All product and engineering specifications were verified and validated.

Software validation was performed to demonstrate that RSI MRI+ processes DICOM images and presents the processed images and quantitative results in DICOM format. In all instances RSI-MRI+ functioned as intended and outputs were created as expected.

Performance testing included protocols demonstrating;

- Increased conspicuity of the RSI-MRI+ *Restricted Signal Map* to standard DWI maps in regions of restricted diffusion
- Accuracy of automated segmentation compared to manual radiologist segmentations
- Diffusion signal normalization across acquisitions and scanners

Retrospective clinical data (including professionally labeled regions-of-interest, T2-weighted anatomical data, and raw diffusion image series) were used for verification and validation of the diffusion analysis (diffusion signal normalization and *Restricted Signal Map* conspicuity).

Nonclinical Testing and Performance Information

Nonclinical and performance testing has been performed by designated individuals as required by HealthLytix quality procedures. Verification & Validation Test Plans were designed to evaluate all input functions, output functions, and actions performed by RSI-MRI+ in each operational mode. RSI-MRI+ has been assessed and tested at the manufacturer's facility and has passed all in-house testing criteria including validating design, function and specifications. Measurement validation was performed on clinically acquired images and shows that RSI-MRI+ is safe and effective. Nonclinical and performance testing results are provided in the 510(k) and demonstrate that the predetermined acceptance criteria are met.

Conclusion:

The results of comparing the intended use, features and functionality, technological characteristics, mode of operation, and specifications of RSI-MRI+ with those of the predicate device demonstrate that RSI-MRI+ is substantially equivalent. Any differences between RSI-MRI+ and the predicate device do not raise any new questions of safety or effectiveness.