MultiFunctional Imaging, LLC
% Dan Kadrmas, Ph.D.
Founder & Chief Science Officer
551 East 50 North
NORTH SALT LAKE UT 84054

February 5, 2018

Re: K173512
Trade/Device Name: MFI-Cardiac
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, KPS
Dated: November 6, 2017
Received: December 7, 2017

Dear Dr. Kadrmas:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number *(if known)*

K173512

Device Name

MFI–Cardiac

Indications for Use *(Describe)*

The MFI–Cardiac application is intended to provide processing of rest and stress myocardial perfusion positron emission tomography (PET) images with approved radiotracers that have been acquired with a single-scan or fast back-to-back scans without waiting for radiotracer decay between scans. The application models measurements of tracer uptake over time to aid in the processing of the images. Co-registration or fusion of volumetric data is provided as a quality control. The processed output images are reviewed on other devices by qualified medical professionals trained in the use of medical imaging devices.

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

Date Prepared: November 6, 2017

1. General

510(k) Sponsor: MultiFunctional Imaging, LLC
551 E 50 N
North Salt Lake, UT 84054

Contact Person: Dan Kadrmas, PhD
Founder and Chief Science Officer
801-953-5655 (phone)
Dan.Kadrmas@MFImage.com (email)

Prepared By: Phil Triolo and Associates, LC

Trade/Device Name:	MFI–Cardiac
Common Name:	Software for processing PET images
Classification Name:	Emission computed tomography system / Picture archiving and communications system
Regulation number:	21 CFR 892.1200 / 21 CFR 892.2050
Product Code:	KPS / LLZ
Predicate Device:	Corridor4DM v2010 (K101279)
Associated FDA Document Number:	Q120397 (Pre-Sub dated Dec. 14, 2012)

2. Device Description

MFI–Cardiac is a software medical device that facilitates the rapid acquisition and processing of rest and stress myocardial perfusion images (MPI) with positron emission tomography (PET) and approved radiotracers. The device processes rest+stress cardiac PET images that have been rapidly acquired using either a single scan with two administrations of the tracer (one at rest, the other at stress) or separate “back-to-back” rest and stress scans. The rapidly acquired rest and stress cardiac PET images are provided to MFI–Cardiac via digital image transfer in DICOM format.

In use, the device first performs a series of quality assurance tests to ensure data integrity and validity. The images are then processed to correct for residual activity from the 1st tracer administration (administered at rest) that affects the image obtained after the 2nd tracer injection (administered at stress). The device then outputs separated and corrected DICOM images at rest and stress; these images are offloaded to other devices for display and review by qualified healthcare professionals.

3. Intended Use

The MFI–Cardiac application is intended to provide processing of the biodistribution of radionuclides in the body using tomographic images. The application models measurements of tracer uptake over time to aid in the processing of myocardial perfusion emission tomographic images. Co-registration or fusion of volumetric data is provided as a quality control. The processed output images are reviewed on other devices by qualified medical professionals trained in the use of medical imaging devices.

The intended use of the new device is the same, but not *identical* to that of the predicate device (Corridor 4DM v2010); however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the subject device relative to the predicate. Both the subject and predicate devices are intended to provide processing of the biodistribution of radionuclides in the body using tomographic images and both are used for rest-stress myocardial perfusion imaging in nuclear cardiology.

4. Technological Comparison with Predicate Device

The chart below compares the subject device MFI–Cardiac to the predicate device Corridor4DM v2010.

Feature	Subject Device (MFI–Cardiac)	Predicate Device (Corridor4DM v2010)
Processes rest-stress myocardial perfusion images	Yes	Yes
DICOM image transfer capabilities	Yes	Yes
Functionality for processing images of two radiotracer administrations during a single scan	Yes	No
Processing of rest and stress myocardial perfusion images in preparation for review	Yes	Yes
Kinetic modeling of tracer uptake over time	Yes	Yes
Quantification of myocardial blood flows	No	Yes
Co-registration of volumetric cardiac images	Yes	Yes

Differences between the new and predicate devices do not raise different questions of safety and effectiveness.

5. Performance Data

The performance data provided in this submission in support of the substantial equivalence determination are described in the subsections below:

Software Verification and Validation

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."* The software for this device is considered to pose a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient.

Performance Evaluations

Three performance evaluation studies were completed with all acceptance criteria met:

(1) Simulation studies to evaluate device performance across the full range of rest and stress myocardial blood flows that are anticipated to be encountered clinically;

(2) Performance evaluation using patient dataset with synthesized rest+stress images to evaluate the performance of MFI–Cardiac for producing output (corrected) rest and stress images that are equivalent to rest and stress images obtained from separate scans; and

(3) Evaluation of rest-stress image co-registrations performed by MFI–Cardiac for ensuring that the estimate for residual rest tracer activity is aligned with the stress-phase images before the correction is applied. This evaluation was also performed using patient datasets with synthesized rest+stress images.

Human Factors / Usability Study

Human factors engineering for MFI–Cardiac included preliminary human factors analyses, formative evaluations, implementation of design changes that mitigate or eliminate use-related hazards, and human factors validation testing. The results of validation testing indicate that MFI–Cardiac is safe and effective for the intended users, uses and use environments. Residual risks that remain would not be further reduced by modifications of user interface design or labeling (User Manual and Supporting Documents), and are outweighed by the benefits that may be derived from the device's use.

6. Conclusion / Summary of Substantial Equivalence

The results of the non-clinical, human factors engineering, and simulated use tests and software verification and validation studies demonstrate the safety and effectiveness of the subject device and equivalence with the predicate device. Based on the information and data provided and analyzed in this 510(k) premarket notification, MultiFunctional Imaging, LLC concludes that MFI–Cardiac is substantially equivalent to the predicate device and is safe and effective for its intended use.