Resoundant, Inc.
% Mr. Bernard Horwath
Regulatory Consultant
HRG
4486 Timberline Ct
VADNAIS HEIGHT MN 55127

August 1, 2019

Re: K183193
Trade/Device Name: MREplus+ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 28, 2019
Received: July 2, 2019

Dear Mr. Horwath:

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)*
K183193

Device Name

MREplus+ Software

Indications for Use *(Describe)*

MREplus+ Software is an assisted ROI drawing tool for liver MRE and Fat/Water images and is used for receiving, display, ROI selection, and analysis generation. It displays to a trained reader MRE and Fat/Water images, preliminary ROIs that it calculates from these images, and statistical analysis calculated from the ROIs and images. ROIs and images are presented in a way for review and, optionally, modification by the trained reader.

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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K183193

510(k) Summary
Resoundant MREplus+ **Software**

Date Prepared: 25 June 2019

Submitter: Resoundant Inc.
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Telephone: 507-322-0011

Contact: Mr. Bernard Horwath
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Vadnais Heights, MN 55127
Telephone: 651- 231-1761

Proprietary Name: MREplus+ Software

Common/Usual Name: System, Image Processing, Radiological

Regulation Name: Picture Archiving and Communications System
21 CFR 892.2050, Class II
Product Code – LLZ System, Image Processing, Radiological

Description:
The MREplus+ software is a tool for assisted Magnetic Resonance Elastography (MRE) and multi-point Dixon Fat/Water (FW) image analysis which calculates preliminary automated regions of interest (ROIs) and provides the environment for the trained readers to review the relevant MRE and FW information and approve or modify the ROIs. MREplus+ is intended to be used only with liver MRE and FW data. The inputs for MREplus+ are the MRE and FW images. In the case of MRE, this includes magnitude images (showing anatomy), wave images (showing wave propagation) with multiple time points across the wave cycle, and the elasticity and confidence images calculated by MRE's on-scanner MMDI algorithm or an offline MMDI packaged with MREplus+. In the case of FW, images include in-phase, out-of-phase, fat, water, fat fraction, and R2*. MREplus+ includes a DICOM receiver which can recognize and accept these images when sent from the MRI scanner or workstation using standard protocols. From these images, MREplus+ calculates automated ROIs. ROIs can be reviewed by an authorized trained reader for review, modification and approval. MREplus+ performs statistical calculations from the ROIs. MREplus+ outputs images, ROIs, and calculated results in an archive compatible report.

Indications for Use: MREplus+ Software is an assisted ROI drawing tool for liver MRE and Fat/Water images and is used for receiving, display, ROI selection, and analysis generation. It displays to a trained reader MRE and Fat/Water images, preliminary ROIs that it calculates from these images, and statistical analysis calculated from the ROIs and images. ROIs and images are presented in a way for review and, optionally, modification by the trained reader.

Substantial Equivalence:
The MREplus+ Software is substantially equivalent to the following predicate device:

Primary Predicate: GE Advantage Workstation 4.1
510(k): K020483 GE Medical Systems
This predicate has not been subject to a design related recall.

Comparison with Predicate:
Both MREplus+ and the predicate software tools display MRE and FW images, provide the tools for drawing a ROI, calculate average stiffness from the ROI area, and allow DICOM archive-compatible images to be generated for the clinical report. ROI selection on both stations must be performed by trained readers. The scope of the GE Advantage Workstation 4.1 is broader, as it allows for display and analysis of images of multiple modalities, whereas MREplus+ works specifically with liver MRE and FW data.

The GE Advantage Workstation (GE AW) comes pre-installed on a dedicated workstation. It receives and stores medical DICOM images of multiple modalities transferred from a device with DICOM push capabilities (such as an MRI or CT scanner, or another GE AW). A trained user is able to select one of the stored image sets and display them using the system. Images from qualitative modalities may be used as an element in diagnosis directly. For quantitative modalities, such as MRE, the user uses the GE Advantage Workstation tools to select an ROI within the image and calculate values, such as size, mean value, or standard deviation, from it. The GE Advantage Workstation outputs the ROIs overlaid over the original images as DICOM images which are archived clinically as part of the report. The values calculated from the ROIs may be recorded by the user and entered into the report manually or be displayed as part of the output images. The clinical report is then used as an element in diagnosis.

MREplus+ is intended to be used only with liver MRE and FW data, so its scope is a subset of the scope of the GE Advantage Workstation. MREplus+ is installed on standard computers, servers, or workstations, which reside on the intranet of the institution and, similarly to the GE AW, have restricted login privileges. MREplus+ receives DICOM medical images transferred from MRI scanners or other sources and automatically pre-processes the received MRE images to generate automated ROIs. An authorized trained user, such as a technician or radiologist, can use MREplus+ to display an MRE or FW exam along with ROIs. The MREplus+ user reviews the ROIs in context of all acquired MRE or FW data, similarly to the fully-manual ROI drawing on the GE AW. The user may perform modifications or, if none are required, approves the ROIs. At this stage, MREplus+ generates and outputs an archive compatible report containing final ROIs overlaid on the input images and the calculated statistical values associated with ROI areas and underlying images.

MREplus+ also supports direct generation of the archive compatible analysis report from the automated ROIs, for presentation to a radiologist in conjunction with other imaging data. This behavior can be enabled by the institution, and does not preclude subsequent review or modification of the ROIs and subsequent analysis.

A comparison of the devices is provided in the following table:

Feature and Technical Characteristic Comparison

Device Parameter	MREplus+ Software	GE Advantage Workstation 4.1	Difference if any
510(k)		K020483	NA
Classification	21 CFR 892.2050, Class II	21 CFR 892.2050, Class II	Same
Product Code	Product Code – LLZ System, Image Processing, Radiological	Product Code – LLZ System, Image Processing, Radiological	Same
Indications for Use	MREplus+ is an assisted ROI drawing tool for liver MRE and Fat/Water images and is used for receiving, display, ROI selection, and analysis generation. It displays to a trained reader MRE and Fat/Water images, preliminary ROIs that it calculates from these images, and statistical analysis calculated from the ROIs and images. ROIs and images are presented in a way for review and, optionally, modification by the trained reader. These values can be used as an element in diagnosis of liver disease.	The Advantage Workstation 4.1 is a review station, which allows selection, review, processing, filming, and media interchange of multi-modality images from a variety of diagnostic imaging systems. When interpreted by a trained physician, filmed images may be used as an element for diagnosis.	Intended use is substantially equivalent. MREplus+ is intended for use with liver MRE and Fat/Water data, which is a subset of the scope of applications for the GE Advantage
Product Configuration	Software	Workstation	MREplus+ is a stand-alone application, whereas GE AW comes pre-installed on dedicated workstations
Operating system	Windows or Linux	Linux	MREplus+ as stand-alone application can

			be configured for different OS, whereas the GE dedicated workstation must select an OS.
Input format	MRE and FW Liver DICOM Images	Multi-modality DICOM Images	DICOM input is the same, with the MREplus+ liver images being a subset of GE multi-modality images
Output	MREplus+ report displays DICOM images which includes the generated ROIs overlaid on the input images, and the calculated liver statistical values	Advantage Workstation 4.1 allows for display of DICOM images of user-drawn ROIs overlaid on input DICOM images, and the calculated liver statistical values	The output images with overlaid ROIs and calculated liver statistical values are substantially equivalent.
Intended User	MRE-trained reader (e.g. technician or radiologist)	MRE-trained reader (e.g. technician or radiologist)	Same

Software Information

The MREplus+ software has been developed in accordance with the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" for moderate level of concern. The Risk Management and Hazard Analysis combined with the appropriate testing and labeling mitigation measures taken indicate that the device is safe and effective and presents no new concerns.

The main activities in the software development process are described as follows.

- Software Description
- Level of Concern
- Hazard/Risk Analysis
- Software Requirements Specification
- Architecture Design Flow Chart
- Software Design Specification
- Traceability Analysis
- Software Development Life Cycle Plan
- Software Development Environment
- Software Design Verification/Validation Test
- Revision Level History
- Unresolved Anomalies

Verification and Validation:
MREplus+ has been extensively tested through the design verification and system validation phases of its development. Validation Testing has been conducted using retrospective clinical data bases to compare MREplus+ 's functional capabilities with the standard expert reviewer readings using the predicate device. Studies included the following:

- MRE study involving 1347 patient cases, where the patient profile included liver disease or suspicion of liver disease, inclusive of all ages, weight, and races. Images were collected at both 1.5T and 3T. MREplus+ demonstrated <1% processing failures and <20% ROI modifications.
- Fat-Water study involving 92 patient cases, where recruited patents were undergoing bariatric surgery and FW results indicated a full range of liver fat content. Images were collected at both 1.5T and 3T. In all cases MREplus+ was able to accurately and reliably calculate Fat Fraction from Fat-Water images.

MREplus+ has consistently proven to be an accurate software tool that facilitates liver MRE analysis with an accuracy of >99% compared to the standard predicate methodology.

Conclusion:
Through the data and information presented, Resoundant Inc considers the MREplus+ Software substantially equivalent to the predicate device already on the market (cleared by the 510(k) process) in terms of indications for use, scientific technology, design, and functional performance and presents no new concerns about safety and effectiveness. The nonclinical and retrospective clinical validation tests conducted demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.