Resoundant, Inc.
% John Hartigan, DRSc. MBA
VP QA/RA
421 First Avenue SW, Suite 204W
ROCHESTER MN 55902

July 10, 2020

Re: K201389
Trade/Device Name: Resoundant Acoustic Driver System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: May 21, 2020
Received: May 27, 2020

Dear Mr. Hartigan:

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)*
K201389

Device Name

Resoundant Acoustic Driver System

Indications for Use *(Describe)*

The Resoundant Acoustic Driver System is intended for use with magnetic resonance diagnostic devices (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam, in order to assess tissue elasticity for diagnostic purposes as part of magnetic resonance elastography (MRE). When interpreted by a trained physician, this information can be useful in determining a diagnosis.

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

K201389

Resoundant Acoustic Driver System

Date Prepared: 7 July 2020

Submitter: Resoundant Inc.
421 First Ave SW
Suite 204W
Rochester, MN 55902
Telephone: 507-322-0011

Contact: John Hartigan, DRSc., MBA
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421 First Ave SW, Suite 204W
Rochester, MN 55902
Telephone: 507-322-0011

Proprietary Name: Resoundant Acoustic Driver System

Common/Usual Name: Acoustic Driver System
Accessory for Magnetic Resonance Image System for MRE

Regulation Name: Magnetic Resonance Image System
21 CFR 892.1000, Class II
Product Code – LNH, Magnetic Resonance Image System, Radiological

Description: The Resoundant Acoustic Driver System includes an Active Driver, connective tubing and a Passive Driver. The system generates transverse acoustic waves in the low-audio frequency range in the body during an MRI exam. This allows assessment of elastic properties of soft tissue to aid in medical diagnosis as part of magnetic resonance elastography (MRE).

The Active Driver component is an electro-mechanical device that consists of a function generator, power-amplifier, linear motor and pump head, along with a microprocessor-based controller and power supply electronics, in an enclosure. The Passive Driver component is connected to the Active Driver through flexible tubing and is used to induce small vibrations in the scan subject. The Passive Driver is a lightweight enclosure containing no electrical components. It features a connection for flexible tubing and a diaphragm that is placed securely over patient clothing.

Indications for Use: The Resoundant Acoustic Driver System is intended for use with magnetic resonance diagnostic devices (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam, in order to assess tissue elasticity for diagnostic purposes as part of magnetic resonance

elastography (MRE). When interpreted by a trained physician, this information can be useful in determining a diagnosis.

Substantial Equivalence:
The Resoundant Acoustic Driver System is substantially equivalent to the following predicate device:

Primary Predicate: GE MR-Touch Option
510(k): K083421 GE Medical Systems
This predicate has not been subject to a design related recall.

Comparison with Predicate:
The predicate, MR-Touch from GE Medical Systems, consists of the Resoundant Active Acoustic Driver System and acquisition/processing software in its MRI system. The hardware portion of the MR-Touch option is the Resoundant Acoustic Driver System, which is identical in intended use and technology/configuration.

All electro-mechanical functional specifications of the proposed Resoundant Acoustic Driver System remain the same as the original Acoustic Driver System utilized in the predicate MR-Touch.

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

Feature and Technical Characteristic Comparison

Device Parameter	Resoundant Acoustic Driver System	GE Mr-Touch Option	Difference if any
510(k)		K083421	NA
Classification	21 CFR 892.1000, Class II	21 CFR 892.1000, Class II	Same
Product Code	Product Code – LNH Magnetic Resonance Diagnostic Device, Radiological	Product Code – LNH Magnetic Resonance Diagnostic Device, Radiological	Same
Indications for Use	The Resoundant Acoustic Driver System is intended for use with magnetic resonance diagnostic devices (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam, in order to assess tissue elasticity for diagnostic purposes as part of	MR-Touch™ is a software and hardware option intended for use with GE Signa® MR systems. it is indicated for magnetic resonance imaging of the human body. MR-Touch™ generates transverse sectional information related to the relative stiffness of soft tissue. It consists of hardware as well as acquisition	Overall Intended Use is substantially equivalent; the acoustic vibration generation is identical. The Acoustic Driver System is the same

	magnetic resonance elastography (MRE). When interpreted by a trained physician, this information can be useful in determining a diagnosis.	and reconstruction software. The hardware components induce vibrations into the scan subject. The MR-Touch™ acquisition software is an evolutionary improvement to the gradient echo sequence. The sequence synchronizes the induced vibrations to acquire a series of phase-contrast images over time. The phase-contrast imaging technique measures motion or displacement. The displacement from the induced vibrations is detected using the time-series of phase-contrast images. The displacement information is reconstructed and presented as strain wave and relative stiffness images. When used with a GE Signa® MR system, MR-Touch™ is capable of producing transverse images of internal body structures such as muscle and liver. When interpreted by a trained physician, these images may provide information that can be useful in determining a diagnosis.	hardware device that generates the acoustic vibrations, enabling MR Elastography.
Vibration Product Configuration	The Resoundant Acoustic Driver System includes the Active Driver, tubing and Passive Driver.	The Resoundant Acoustic Driver System includes the Active Driver, tubing and Passive Driver.	Same
Output	Nominally 60 Hz with a range of 20-350 Hz	Nominally 60 Hz with a range of 20-350 Hz	Same
Intended User	MRE-trained technician or radiologist	MRE-trained technician or radiologist	Same

Verification and Validation:
The Resoundant Acoustic Driver System has been extensively tested through the design verification and system validation phases of its development. The following provides an overview of the testing successfully performed:

- Mechanical Testing: Dimensional, operational performance, and material testing was performed to assure compliance to specifications.
- Electrical Testing: Testing was conducted by an authorized third party laboratory to verify compliance of the Acoustic Driver System to product specifications as well as the following international standards for Safety for Medical Electrical Equipment: IEC ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 and IEC 60601-1-2:2014 (Fourth Edition).
- Firmware: The firmware utilized in the Active Driver microprocessor was developed and tested to assure compliance to specifications.
- Packaging: The packaged Acoustic Driver System was tested to verify that the packaging and product was not damaged during processing, shipping, or storage when subjected to simulated distribution testing per ASTM D4169-*16 Distribution C*ycle 13.

Conclusion:
Through the data and information presented, Resoundant Inc. considers the Acoustic Driver System 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 verification and validation tests conducted demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device for its intended use.