February 12, 2025

Quality Electrodynamics, LLC
Eric Yeh
Senior Regulatory Affairs Specialist
6655 Beta Drive, Suite 100
Mayfield Village, Ohio 44143

Re: K242006
Trade/Device Name: SureWave Elastography (Q7000225)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: December 27, 2024
Received: December 27, 2024

Dear Eric Yeh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242006

Device Name

SureWave Elastography (Q7000225)

Indications for Use *(Describe)*

The SureWave Elastography device is intended for use with Siemens 1.5T and 3.0T MRI systems to generate shear wave vibrations in the body of adult patients during an MRI exam that are translated into images representing tissue stiffness. The images may be used for diagnostic purposes when interpreted by a trained physician.

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 – SureWave Elastography

1. Contact Details

a. Applicant Name
Quality Electrodynamics, LLC

b. Applicant Address
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Mayfield Village, OH 44143

c. Applicant Contact Telephone
440-484-2940

d. Applicant Contact
Mr. Eric Yeh

e. Applicant Contact Email
eric.yeh@qualedyn.com

2. Device Name

a. Device Trade Name
SureWave Elastography (Q7000225)

b. Common Name
Magnetic resonance diagnostic device

c. Classification Name
System, Nuclear Magnetic Resonance Imaging

d. Regulation Number
892.1000

e. Product Code(s)
LNH

3. Legally Marketed Predicate Devices

a. K201389, Resoundant Acoustic Driver System, Product Code LNH
b. K140666, MR Elastography, Product Code LNH

4. Device Description Summary

The SureWave Elastography device is an accessory to the MRI system comprised of both hardware and software components. The hardware induces shear wave vibrations in the body through a transducer which is driven by a mobile tower and two flexible rotating axes. The transducer is fastened to the patient's body and contains a rotatable eccentric mass which induces vibrations in the body during an MRI scan. The SureWave Elastography reconstruction software uses the acquired image data from the MRI system to create images that show tissue stiffness.

5. Intended Use/Indications for Use

The SureWave Elastography device is intended for use with Siemens 1.5T and 3.0T MRI systems to generate shear wave vibrations in the body of adult patients during an MRI exam that are translated into images representing tissue stiffness. The images may be used for diagnostic purposes when interpreted by a trained physician.

6. Indications for Use Comparison

The Indications for Use statement for the SureWave Elastography is not identical to that of the predicate devices (Resoundant Acoustic Driver System and MR Elastography); however, the differences do not affect the safety or effectiveness of the device relative to the predicate devices. Both Indications for Use statements for the proposed SureWave Elastography and predicate Resoundant Acoustic Driver System indicate that the device is intended to be used in conjunction with a MR system to produce images representing tissue stiffness of the body anatomy and that the images can be interpreted by a trained physician. Furthermore, both apply MR acquisition sequence synchronized with an external source of vibration to produce said images representing tissue stiffness, and are both compatible with magnetic resonance diagnostic devices (MRDD) including MRI systems. The indications for use statements differ only in that the proposed SureWave Elastography has external source of vibration (shear waves) instead of acoustic vibration and achieves this via tower, transducer and axes instead of active driver, tubing and passive driver.

7. Technological Comparison

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

- Intended to apply external source of vibration to produce images representing tissue stiffness (in kiloPascals, kPa)

- Applies MR acquisition sequence synchronized with an external source of vibration

- Compatible with magnetic resonance diagnostic devices (MRDD) including MRI systems

- Core images of stiffness maps, confidence overlay, and wave images are provided.

The following technological differences exist between the proposed and predicate device:

- External source of vibration is shear waves (proposed device) versus acoustic vibration (predicate device 1)

- Tower, transducer and axes (proposed device) versus Active Driver, tubing and Passive Driver (predicate device 1)

- Inversion algorithm offers 2D and 3D solutions (proposed device) versus 2D solution only (predicate device 2)

Note that the hardware used in predicate 1 and predicate 2 are identical. Predicate 2 is included here because it also provides a software solution.

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

Bench testing was completed to determine the repeatability and accuracy of the SureWave Elastography device compared to the predicate device.

MRE acquisitions from SureWave Elastography 2D, SureWave Elastography 3D, and the predicate MRE methods were compared against known stiffness values using a multi-component elasticity QA phantom containing three different elements with expected stiffness values established by the phantom manufacturer. Acquisitions were performed on a Siemens 3T system using sequences intended for use with each MRE method. Known stiffness values ranged from 2.02 to 5.8 kPa.

The results show that the stiffness values obtained with SureWave Elastography 2D and 3D methods fall between the stiffness values obtained from the predicate method and the expected stiffness value as determined

by the QA elastography phantom manufacturer. Therefore, the computed stiffness values obtained from the SureWave Elastography methods were at least as accurate if not more accurate than the predicate method and the three methods can be considered equivalent.

SureWave Elastography 2D, SureWave Elastography 3D, and the predicate MRE methods were also used to acquire multiple repeated measurements using a general QA phantom to determine repeatability. 240 measurements were acquired from each method. The repeatability of all three methods was found to be within 10% of the mean of the respective method. Repeatability of the SureWave Elastography was slightly better than that of the predicate.

The data was combined to determine the expected accuracy of SureWave Elastography. Based on the data, see table below for expected accuracy of SureWave Elastography 2D and 3D.

Expected Value (kPa)	**Measured Value (kPa)**	
	SureWave 2D*	**SureWave 3D***
0.82	0.76 ± 0.01	0.73 ± 0.02
2.02	2.53 ± 0.94	2.01 ± 0.07
2.77	3.83 ± 0.44	3.27 ± 0.32
5.80	5.80 ± 0.67	5.20 ± 0.09

* 95% confidence interval

Equivalency of SureWave Elastography results compared to the predicate device was verified through volunteer testing. SureWave Elastography 2D and 3D as well as the predicate device were used to collect images and stiffness measurements from a total of 22 healthy adult volunteers. The stiffness measurements obtained from the SureWave Elastography 2D and 3D were separately plotted against the predicate device. Linear regression was then applied to assess the relationship between the two methods and Bland-Altman plots were used to evaluate the bias between the two methods.

The SureWave Elastography 2D versus the predicate device plot showed excellent agreement between the two methods. The linear regression had a slope of 1.02 (R2 = 0.99) and the Bland-Altman plot showed a bias of 4%. Therefore, no significant difference was observed between SureWave Elastography 2D and the predicate device; the two methods are equivalent.

The linear regression of SureWave Elastography 3D versus the predicate device showed a strong linear relationship (R2 = 0.99) between the SureWave Elastography 3D technique and the predicate device. The linear regression slope and Bland-Altman plots indicated a bias of approximately 20% between the two methods. The 3D image uses volumetric analysis instead of the 2D single slice analysis, therefore, a bias in stiffness measurements between 2D to 3D was expected. The non-clinical testing and literature indicates that the 3D measurements may actually be more accurate than the 2D measurements.

The electrical safety and electromagnetic compatibility and biocompatibility data support the safety of the SureWave Elastography. The bench and clinical testing show that SureWave Elastography produces highly reproducible stiffness measurements consistent with those obtained from the predicate device and industry standard. This testing demonstrates that the SureWave Elastography is substantially equivalent to the predicate device.