Canon Medical Systems Corporation
℅ Mr. Paul Biggins
Sr. Dir. Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive
TUSTIN CA 92780

March 3, 2022

Re: K220018
Trade/Device Name: MR Elastography; MZEK-001A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: December 29, 2021
Received: January 5, 2022

Dear Mr. Biggins:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220018

Device Name
MR Elastography; MZEK-001A

Indications for Use *(Describe)*
MR Elastography is an optional package for Canon Medical Systems magnetic resonance imaging (MRI) systems. This option allows the user to obtain an image that reflects the stiffness, in kPa, of body tissue such as liver and muscle.

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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K220018

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

1. CLASSIFICATION and DEVICE NAME

Classification Name:	**Magnetic Resonance Diagnostic Device**
Regulation Number:	**90-LNH (Per 21 CFR § 892.1000)**
Trade Proprietary Name:	**MR Elastography**
Model Number:	**MZEK-001A**

2. SUBMITTER'S NAME

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. OFFICIAL CORRESPONDENT

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4. CONTACT PERSON, U.S. AGENT and ADDRESS

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5. MANUFACTURING SITE

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. ESTABLISHMENT REGISTRATION

9614698

7. DATE PREPARED

December 29, 2021

8. DEVICE NAME

MR Elastography, MZEK-001A

9. TRADE NAME

MR Elastography, MZEK-001A

10. CLASSIFICATION NAME

Magnetic Resonance Diagnostic Device (MRDD)

11. CLASSIFICATION PANEL

Radiology

12. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1000, Magnetic Resonance Diagnostic Device)

13. PRODUCT CODE

90-LNH

14. PREDICATE DEVICE

Predicate Device:

- MR Elastography (K140666)

Reference Devices:

- Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K193215)
- MR Elastography, Resoundant (K201389)

System	Subject Device	Predicate Device	Reference Device	Reference Device
	MR Elastography	MR Elastography	Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems	MR Elastography
Marketed By	Canon Medical Systems USA, Inc.	Philips	Philips	Resoundant
510(k) Number	This Submission	K140666	K193215 (Referred to MR Elastography extension)	K201389
Clearance Date		June 13, 2014	April 10, 2020	July 10, 2020

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Traditional 510(k) Premarket Notification

17. DEVICE DESCRIPTION

MR Elastography is an optional package for Canon Medical Systems magnetic resonance imaging (MRI) system. This option allows the user to obtain an image that reflects the stiffness of body tissue.

MR Elastography consists of Acoustic Driver System including Active Driver, Passive Driver, QA Phantom and Other parts, TTL trigger converter includes AC adaptor, Manuals and Software (License).

By MRI scanning while applying vibration from the Acoustic Driver System, it is possible to obtain an image that reflects the stiffness of the body tissue in kPa. The sequence to be used with Acoustic Driver System is FE2D or SE-EPI2D. The MRI scanner outputs the following images from the acquired phase image and magnitude image.

・Wave image
・Stiffness image (capable of registration and display in color image format)
・Confidence image (capable of superimposing confidence image on the stiffness image)

18. SUMMARY OF CHANGE(S)

This submission is to report the following functionalities have been added:

Summary of Hardware Changes:

- **MR Elastography:**

  MR Elastography consists of Acoustic Driver System including Active Driver, Passive Driver, QA Phantom and Other parts, TTL converter includes AC adaptor.

Summary of Software Changes:

- **MR Elastography:**

  MR Elastography is a newly added optional package that allows the user to obtain an image that reflects the stiffness of body tissue.

  By MRI scanning while applying vibration from the Acoustic Driver System, it is possible to obtain an image that reflects the stiffness of the body tissue in kPa. The sequence to be used with Acoustic Driver System is FE2D or SE-EPI2D. The MRI scanner outputs the following images from the acquired phase image and magnitude image.

  ・Wave image
  ・Stiffness image (capable of registration and display in color image format)
  ・Confidence image (capable of superimposing confidence image on the stiffness image)

19. INDICATIONS FOR USE

MR Elastography is an optional package for Canon Medical Systems magnetic resonance imaging (MRI) systems. This option allows the user to obtain an image that reflects the stiffness, in kPa, of body tissue such as liver and muscle.

20. SUMMARY OF DESIGN CONTROL ACTIVITIES

Risk Management activities for new software functionality is included in this submission. A declaration of conformity with design controls is included in this submission.

21. SAFETY

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards.

This modification is based upon the same technologies, materials, and software as the target Canon MRI systems. Risk activities were conducted in concurrence with established medical device development standards and guidance.

22. TECHNOLOGICAL CHARACTERISTICS:

MR Elastography contains both hardware and software elements. The hardware elements are supplied by Resoundant, Inc. (K201389) and consist of an active driver positioned outside the magnet room and a passive driver positioned on the scan subject. The MR Elastography software post-processing package was based on an estimation algorithm provided by the Mayo Clinic and Resoundant, Inc. and the final MR Elastography software was developed in conjunction with The Mayo Clinic and Resoundant, Inc. The Philips MR Elastography (K140666) and Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K193215) contain the same hardware elements provided by Resoundant, Inc. and used the same estimation algorithm and worked in conjunction with the Mayo Clinic and Resoundant, Inc. to develop the final software. The GE IDEAL IQ SOFTWARE OPTION (K103411) and MR-TOUCH OPTION (K083421), and the SIEMENS SOFTWARE SYNGO MR D13A FOR THE MAGNETOM SYSTEMS AERA/SKYRA/AVANTO/VERIO (K121434) and MAGNETOM AERA WITH SOFTWARE SYNGO MR E11A, MAGNETOM SKYRA WITH SOFTWARE SYNGO MR E11A, MAGNETOM SKYRA WITH 24 RF CHANNEL (K141977) are as well.

The phase contrast imaging sequences to be used for the MR Elastography data process are substantially equivalent to the existing phase contrast imaging sequences which was previously cleared Vantage Orian 1.5T, MRT-1550, V7.0 (K211633, K203053) and Vantage Galan 3T, MRT-3020, V7.0 (K212056). The acquisition, processing and output images are substantially equivalent to the previously cleared predicate, Philips MR Elastography (K140666) and Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K193215). As with the above predicate, the MR Elastography option provides for a sensitive phase-contrast acquisition synchronized with the vibration supplied by the Resoundant hardware. This captures images of the tissue displacements, which are then input to an algorithm to estimate tissue stiffness.

23. TESTING

MR Elastography (MRE) performance testing (bench testing), using three Resoundant-provided calibration phantoms having known stiffness values representing the expected clinical range, was conducted to measure tissue stiffness, based on the 2D Multi-Modality Direct Inversion (MMDI) algorithm. The phantoms were scanned 5 times per day, multiple days per scanner, on 2 different 1.5T and 2 different 3T scanners by FE2D and SE-EPI2D techniques. Results of the study demonstrated that a calculated slope of measured stiffness mean value and reference stiffness value by linear regression analysis as well as a 95% confidence limit of measured vs. reference value, by Bland Altman analysis were within the acceptance criteria of 1.0±0.1 (slope) and 95% confidence limits within ±10%.

24. SUBSTANTIAL EQUIVALENCE

Canon Medical Systems Corporation believes that the MR Elastography is substantially equivalent to the previously cleared predicate device, MR Elastography (K140666), MR Elastography of Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K193215), using with Canon MRI systems, referenced in this submission.

Canon Medical Systems Corporation believes that the MR Elastography option added to Canon MRI systems are substantially equivalent to the previously cleared predicate device.

25. CONCLUSION

The MR Elastography indications for use along with, technological characteristics, safety and performance testing, verifies that the subject device meets the requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate and reference devices.