August 26, 2024

Myocardial Solutions, Inc.
Linda Horne
Regulatory Affairs Director
808 Aviation Parkway Suite 700
Morrisville, North Carolina 27560

Re: K241607
Trade/Device Name: MyoStrain (6.0)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: July 26, 2024
Received: July 30, 2024

Dear Linda Horne:

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.

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
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)*

K241607

Device Name

MyoStrain (6.0)

Indications for Use *(Describe)*

MyoStrain® software is an image processing device that post-processes strain-encoded (SENC) images, which are acquired by MRI systems equipped with a SENC pulse sequence. MyoStrain software receives SENC images from MRI storage and archives, and performs extraction of time-resolved, quantitative strain information per voxel and other cardiac measurements, viewing, image manipulations, communications, and printing. Available measurements include longitudinal and circumferential strain to quantitatively describe the wall motion of the heart. Tools are provided to display regional motion properties of the heart. A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of a cardiac imaging exam with strain. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians to support the determination of 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Myocardial Solutions
MyoStrain®
(per 21CFR 807.92)
K241607

I. SUBMITTER

Myocardial Solutions Inc.
808 Aviation Parkway Suite 700
Morrisville, NC 27560

Telephone: 919-459-9102
Fax: 919-882-1815

Contact Person: Linda Horne
Date Prepared: June 04, 2024

II. DEVICE

Name of Device: MyoStrain (6.0)
Common or Usual Name: MyoStrain
Classification Name: Magnetic resonance diagnostic device (21 CFR 892.1000)
Regulatory Class: II
Product Code: LNH

III. PREDICATE DEVICE

MyoStrain (5.1.2) - K182756

IV. DEVICE DESCRIPTION

The Myocardial Solutions Myostrain is software that runs on Windows-based operating systems to view and analyze SENC MR images of the heart in DICOM format. MyoStrain quantifies regional and global cardiac function from SENC images by implementing the SENC processing methods. With a friendly graphic user interface, users are able to analyze SENC MR images and obtain fast and reproducible measurements of myocardial strain, ejection fraction, and

volumes. Measurements are collected and presented on screen as a report showing values as colors and numbers, and this report can be printed or exported in digital format.

V. INDICATIONS FOR USE

MyoStrain® software is an image processing device that post-processes strain-encoded (SENC) images, which are acquired by MRI systems equipped with a SENC pulse sequence. MyoStrain software receives SENC images from MRI storage and archives, and performs extraction of time-resolved, quantitative strain information per voxel and other cardiac measurements, viewing, image manipulations, communications, and printing. Available measurements include longitudinal and circumferential strain to quantitatively describe the wall motion of the heart. Tools are provided to display regional motion properties of the heart.
A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of a cardiac imaging exam with strain. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians to support the determination of a diagnosis.

The indications for Use statement for MyoStrain is identical to the predicate device

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for the subject and the predicate device is based on the use of the same feature of MR tagging to generate temporary spatial modulation of magnetization in the tissue. These MR tagging deforms with contraction and relaxation of the myocardium and can, therefore, be used to track and quantify the deformation. Both the subject and predicate device measure deformation in the form of cardiac strain computed from the MRI images. At a high level, the subject and predicate devices use the following same technological elements:

- MR Tagging Pulse Sequences: Both uses images acquired by MRI pulse sequences based on MR Tagging
- Produce measurements of strain, specifically the longitudinal and circumferential strains
- Use of a Standalone computer system

The following technological difference exist between the subject and the predicate devices:

- Updated Graphical Interface
- New measurements based off the strain measurements of the predicate device:
    - Percentages of segments with normal strain for the left and right ventricles (MyoHealth scores).
    - Regional Strain timing metrics
- New presentations of the measurements of the predicate device:
    - 3-Dimensional Heart Model of the Ventricles
    - Polar Plots of Strain

VII. PERFORMANCE TESTING

The following performance data was conducted and is documented in the concise summary of design controls

Software Verification and Validation Testing

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."

VIII. CONCLUSION

Based on the same indication for use, and similarities in design, functional, and operational features MyoStrain 6.0 has demonstrated substantial equivalence to the listed legally marketed predicate device and any differences do not affect the product's safety or effectiveness.