Myocardial Solutions
% Ms. Linda Horne
Regulatory Affairs Specialist
3000 RDU Center Drive, Suite 117
MORRISVILLE NC 27560

February 14, 2019

Re: K182756
Trade/Device Name: MyoStrain 5.1
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 15, 2019
Received: January 16, 2019

Dear Ms. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182756

Device Name

MyoStrain 5.1

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 of 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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)

I. SUBMITTER

Myocardial Solutions Inc.
3000 RDU Center Drive
Suite 117
Morrisville, NC 27560

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

Contact Person: Linda Horne
Date Prepared: September 26, 2018

II. DEVICE

Name of Device: MyoStrain 5.1
Common or Usual Name: MyoStrain
Classification Name: Magnetic resonance diagnostic device (21 CFR 892.1000)
Regulatory Class: II
Product Code: LNH

III. PREDICATE DEVICE

Harp 2.06 marketed by Diagnosoft, Inc., K100352
This predicate has not been subject to a design-related recall

Reference Device
Virtue marketed by Diagnosoft, Inc. K111833
This reference device has not been subject to a design related recall

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 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 of 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 not identical to the predicate device: however, the difference do not alter the intend use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the diagnosis of cardiac issues by analyzing cardiac MRIs.

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 running Windows 7, 8.1 or 10

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

- The subject has the MR Tagging planes parallel to the imaging slice, therefore producing what is called strain-encoded (SENC) MRI images, while predicate device uses MR Tagging orthogonal to the imaging plane

- The subject measures the strain in the through-plane direction, while the predicate device measures it in the in-plane directions.
- The SENC images used in the subject device are acquired in as fast as one heartbeat acquisition, which is much faster than typical MR Tagging acquisition used in the predicate device.

VII. ACCURACY OF MYOSTRAIN MEASUREMENTS

The accuracy of MyoStrain measurements are determined by the Limit of Agreement (LOA). The LOA is the range that covers the 95% of differences between the measurement of the two devices. For example, if MyoStrain measures LVEF of 67%, the LOA of (-13,+10) means that 95% for a large number LVEF values of the same subject measured using the gold standard Cine MRI will lie between 54% and 77%. The LOA depends on many factors, including images quality and inter-operator and inter-observer variabilities. This LOA was originally based on two predicate devices (Diagnosoft HARP for Strain, Diagnosoft VIRTUE for traditional measurements), however these ranges have been reduced to reflect measured accuracy in MyoStrain.

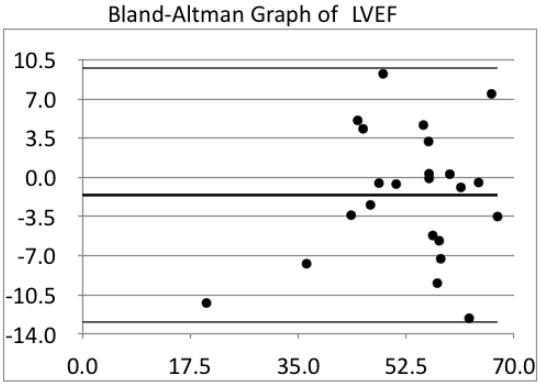
To demonstrate the accuracy of MyoStrain measurements, we calculated the correlation coefficients using Diagnosoft VIRTUE 5.51 measurements of the LV EF, End-Diastolic Volume (EDV), End-Systolic Volume (ESV), Mass, and Stroke Volume (SV). We considered the measurements accurate by requiring that the variations in global measurements due to workstation and user variability to be within the accepted cutoffs of published guidelines and clinical results. We specified that targeted correlation coefficients of the global measures generated by MyoStrain, in comparison to the gold standard cardiac MRI, must be equal or better than the following: EF: $R=0.79$, $p<0.001$, EDV: $R=0.84$, $p<0.001$, ESV: $R=0.94$, $p<0.001$, SV: $R=0.31$, $p=0.05$.
Since the LV Mass is similar to LV volumes, we decided that the R and p values follow the same criteria for EDV. Our acceptance criteria required the following bounds for the 95% range of measurements differences between MyoStrain and Diagnosoft VIRTUE:

- LVEF: (-20,+20)
- LVEDV: (-45,+45)
- LVESV: (-25,+25)
- LVSV: (-40, +40)
- LVMass: (-35, +35)

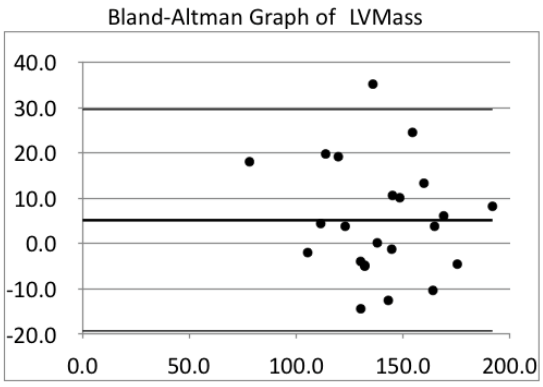
Based on a sample size N=23 of healthy subjects and patients, MyoStrain demonstrated the following *acceptable* LOA:

- LVEF: (-13,+10)
- LVEDV: (-40,+35)
- LVESV: (-19,+21)
- LVSV: (-36,+29)
- LVMass: (-19,+30)

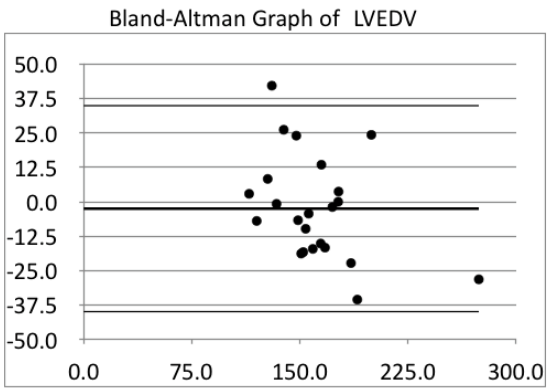
The Bland-Altman Graphs of these calculations can be seen below:



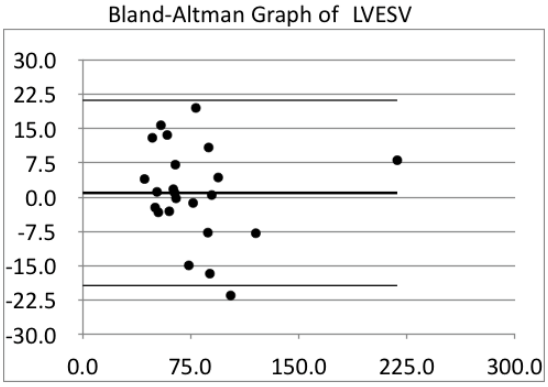
LVEF Limits of Agreement (LOA) is (-13,10)



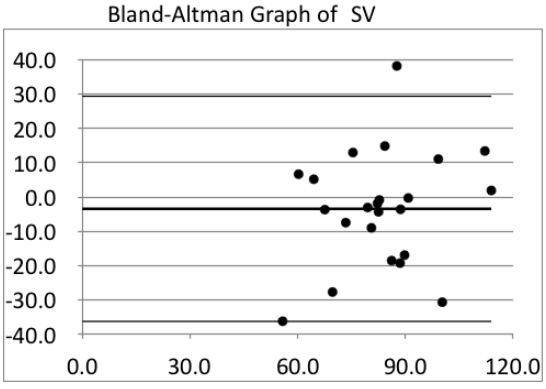
LVMass Limits of Agreement (LOA) is (-19,30)



LVEDV Limits of Agreement (LOA) is (-40,35)



LVESV Limits of Agreement (LOA) is (-19,21)



SV Limits of Agreement (LOA) is (-36,29)

The LOA and accuracy of Strain calculations were based on tests using a mechanical phantom with known actual strain values. Phantom analysis demonstrated that MyoStrain has the *acceptable* LOA of (-5,+5). Note that LOA of MyoStrain of Strain measured *in vivo* in humans is unknown could be different.

The aforementioned accuracies of measurements are associated with images that were correctly acquired and analyzed by trained operators. It is the responsibility of the trained MRI operator and MyoStrain users to check the quality of the acquired images before post-processing them using MyoStrain.

VIII. PERFORMANCE TESTING

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation

Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device. This includes a hazard analysis, where the potential hazards have been classified as a moderate level of concern (LOC). The reported documentations include:

- Software Device Description
- Hazard Analysis
- Software Requirements Definition (SRD)
- Software Architecture Description
- Software Verification and Validation
- Validation of MyoStrain's Algorithm
- Verification of Traditional Global Measurements against Reference Device, Diagnosoft VIRTUE
- Verification of Strain measurements against Predicate Device, Diagnosoft HARP
- Cyber security Documents

Performance Verification

- Integration Testing
- GUI and Report Translation
- Integration with Philips 5.6 MRI System when reading SENC Images
- Philips Healthcare MR Implementation of the SENC Pulse Sequence

Biocompatibility

Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)

Not Applicable to the proposed device, because the device is stand-alone software.

Animal Study

No animal study was required.

Clinical Studies

No clinical study was required.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above. MyoStrain was found to have a safety and effectiveness profile that is similar to the predicate device.

IX. CONCLUSION

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