Siemens Medical Solutions USA, Inc.                          March 30, 2018
Cordell Fields
Regulatory Specialist
65 Valley Stream Parkway Mailcode 65-1A
Malvern, Pennsylvania 19533

Re: K173617
   Trade/Device Name: MAGNETOM Vida with Compressed Sensing GRASP-VIBE
   Regulation Number: 21 CFR 892.1000
   Regulation Name: Magnetic Resonance Diagnostic Device
   Regulatory Class: Class II
   Product Code: LNH, LNI, MOS
   Dated: March 6, 2018
   Received: March 7, 2018

Dear Cordell Fields:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

Compressed Sensing GRASP-VIBE is intended to be used in dynamic and/or non-contrast liver examinations to support patients who cannot reliably hold their breath for a conventional breath-hold measurement.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

*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
PRASStaff@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.”
Section 5 510(k) Summary

This 510(k) 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.

5.1 General Information

Establishment: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: November 21, 2017

Manufacturer: Siemens Healthcare GmbH
Henkestrasse 127
Erlangen, Bayern, Germany 91052
Registration Number: 3002808157

Contact Person: Cordell L. Fields, Esq
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.

Device Name: MAGNETOM Vida with Compressed Sensing GRASP-VIBE

Trade Name: MAGNETOM Vida with Compressed Sensing GRASP-VIBE

Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1000
Classification: Class II
Product Code: Primary: LNH, Secondary: LNI, MOS
5.2 Information Supporting Substantial Equivalence

DEVICE DESCRIPTION
The subject device, MAGNETOM Vida, is an MR system. The software syngo MR XA10A is the latest software for the Siemens MAGNETOM Vida and includes software sequences, applications, coils and other hardware for the MAGNETOM scanner. The software sequences, applications, coils and other hardware were previously cleared with K170396.

MAGNETOM Vida will be offered ex-factory (new production) with software syngo MR XA10A and Compressed Sensing GRASP-VIBE. Installed MAGNETOM Vida systems can be updated by activating the blocked license.

This filing describes the new imaging feature intended to be used with the MAGNETOM Vida. Compressed Sensing GRASP-VIBE is intended to be used in dynamic and/or non-contrast liver examinations to support patients who cannot reliably hold their breath for a conventional breath-hold measurement.

INTENDED USE
Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

Compressed Sensing GRASP-VIBE is intended to be used in dynamic and/or non-contrast liver examinations to support patients who cannot reliably hold their breath for a conventional breath-hold measurement.
Technological Characteristics
The MR system MAGNETOM Vida with Compressed Sensing GRASP-VIBE has one different technological characteristic (Compressed Sensing GRASP-VIBE) compared to the predicate device MAGNETOM Vida (K170396; cleared June 14, 2017). While there is a feature that varies with respect to the predicate device MR System, the conclusions from all verification and validation data suggest that the feature bears an equivalent safety and performance profile as that of the predicate device and the reference devices.

The subject device is substantially equivalent to the predicate device with regard to the software, hardware, operational environment, programming language, operating system and performance.

MAGNETOM Vida conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

NONCLINICAL TESTS
The following performance testing was conducted on the subject device:

- A comparison of the functionality was performed between the new feature and the reference device feature by detailed simulations with a numerical phantom.
- Software verification and validation testing was completed in accordance with the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
- Performance tests were completed in accordance with the FDA guidance document, “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices” dated November 18, 2016
- No testing in accordance with the applicable Performance Standards (NEMA) is needed due to the nature of the new imaging feature (software change only).

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

CLINICAL TESTS
Sample clinical images, rather than a clinical study, were included in the determination of substantial equivalence.
SUBSTANTIAL EQUIVALENCE

The MAGNETOM Vida with software syngo MR XA10A including the new imaging feature Compressed Sensing GRASP-VIBE is substantially equivalent to the following predicate device, described in Table 1.

Table 1: Predicate and reference devices for MAGNETOM Vida with software syngo MR XA10A including Compressed Sensing GRASP-VIBE

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>FDA Clearance Number</th>
<th>FDA Clearance Date</th>
<th>Main Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software syngo MR XA10A for the MR System MAGNETOM Vida</td>
<td>K170396</td>
<td>June 14, 2017</td>
<td>LNH, LNI, MOS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference Devices</th>
<th>FDA Clearance Number</th>
<th>FDA Clearance Date</th>
<th>Main Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>syngo MR E11A for MAGNETOM Skyra</td>
<td>K141977</td>
<td>November 19, 2014</td>
<td>LNH, LNI, MOS</td>
</tr>
<tr>
<td>syngo MR D13C for MAGNETOM Skyra</td>
<td>K123510</td>
<td>May 17, 2013</td>
<td>LNH</td>
</tr>
</tbody>
</table>

The subject device, MAGNETOM Vida, has been modified to include the new imaging feature, Compressed Sensing GRASP-VIBE. No other software modifications have been made, and there are no hardware changes.

SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized in hardware and software development, testing and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards, such as the IEC 60601-1 series, to minimize electrical and mechanical risk. Furthermore, the operators are healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Vida with software syngo MR XA10A conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document as stated in the following table.
<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Product Area</th>
<th>Title of Standard</th>
<th>Reference Number and date</th>
<th>Standards Development Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-271</td>
<td>Radiology</td>
<td>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</td>
<td>60601-2-33 Ed. 3.1:2013</td>
<td>IEC</td>
</tr>
<tr>
<td>5-40</td>
<td>General</td>
<td>Medical devices - Application of risk management to medical devices</td>
<td>14971 Second edition 2007-10</td>
<td>ISO</td>
</tr>
<tr>
<td>5-96</td>
<td>General</td>
<td>Medical devices – Application of usability engineering to medical devices</td>
<td>62366 Edition 1.0 2015</td>
<td>AAMI ANSI IEC</td>
</tr>
<tr>
<td>13-32</td>
<td>Software</td>
<td>Medical device software - Software life cycle processes</td>
<td>62304:2006</td>
<td>AAMI ANSI IEC</td>
</tr>
<tr>
<td>12-232</td>
<td>Radiology</td>
<td>Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices</td>
<td>MS 4-2010</td>
<td>NEMA</td>
</tr>
<tr>
<td>12-288</td>
<td>Radiology</td>
<td>Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)</td>
<td>MS 9-2008</td>
<td>NEMA</td>
</tr>
<tr>
<td>12-300</td>
<td>Radiology</td>
<td>Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology</td>
<td>PS 3.1 - 3.20 (2016)</td>
<td>NEMA</td>
</tr>
<tr>
<td>2-156</td>
<td>Biocompatibility</td>
<td>biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)</td>
<td>10993-1:2009/(R) 2013</td>
<td>AAMI ANSI ISO</td>
</tr>
</tbody>
</table>
SUBSTANTIAL EQUIVALENCE CONCLUSION

The MR system MAGNETOM Vida with software syngo MR XA10A with the new imaging feature Compressed Sensing GRASP-VIBE has the same intended use and one different technological characteristic compared to the predicate device system, MAGNETOM Vida with syngo MR XA10A, with respect to the magnetic resonance features and functionalities. While there is a feature that varies with respect to the predicate device MR System, the conclusions from all verification and validation data suggest that the feature bears an equivalent safety and performance profile as that of the predicate device and the reference devices. The new imaging feature offers the user additional possibilities to perform examinations. The modification aims to improve the user’s workflow and reduces the complexity of the imaging procedure.

In summary, MAGNETOM Vida has the same functionalities as the predicate device and, based on the aforementioned information, does not introduce any new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Vida with software syngo MR XA10A with Compressed Sensing GRASP-VIBE does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed device MAGNETOM Vida with software syngo MR XA10A (K170396 cleared on June 14, 2017).