November 16, 2018

RAPID Biomedical GmbH
Christian Zimmermann
QM & Official Correspondent
Kettelerstrasse 3-11
97222 RIMPAR, BAVARIA, GERMANY

Re: K181948
Trade/Device Name: 1.5 T 16Ch Diagnostic Breast Coil – P-H16LE-015-01811,
3.0 T 16Ch Diagnostic Breast Coil – P-H16LE-030-01630
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: August 2, 2018
Received: September 17, 2018

Dear Christian Zimmermann:

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,

for
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

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)*

K181948

Device Name

1.5 T 16Ch Diagnostic Breast Coil – P-H16LE-015-01811
3.0 T 16Ch Diagnostic Breast Coil – P-H16LE-030-01630

Indications for Use *(Describe)*

The 16Ch Diagnostic Breast Coils are indicated for use as diagnostic imaging device extensions for GE 1.5 T MR Systems and GE 3.0 T MR Systems to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that displays the internal structure of the breast. These images when interpreted by a trained physician, yield information that may assist in 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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

General Information

Date of summary preparation: 2018-11-15

1. **Manufacturer**
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   FEI: 3005049692
2. **Distributed by**
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   FEI: 2124823
3. **Contact Person**
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4. **Type of Submission**
   Traditional 510(k) Premarket Notification
5. **Classification and Device Name**
   Classification Panel: Radiology
   Classification Name: Magnetic Resonance Diagnostic Device Accessory
   Device Class: Class II [21 CFR § 892.1000]
   Product Code: MOS
   Product Nomenclature: Coil, Magnetic Resonance, Specialty
   Common Name: Special Purpose Coil
   Trade Names:
   1.5 T 16Ch Diagnostic Breast Coil and 3.0 T 16Ch Diagnostic Breast Coil

Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use

The 16Ch Diagnostic Breast Coils are indicated for use as diagnostic imaging device extensions for GE 1.5 T MR Systems and GE 3.0 T MR Systems to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that display the internal structure of the breast. These images when interpreted by a trained physician yield information that may assist in diagnosis.

Device Description

The 16Ch Diagnostic Breast Coil (1.5 T 16Ch Diagnostic Breast Coil and 3.0 T 16Ch Diagnostic Breast Coil) is designed for use with a magnetic resonance (MR) system. The coil is designed to work in unison with the Body Coil (BC) of the MR system, which will excite the hydrogen (1H) nuclei with radio frequency (RF) magnetic fields, so that the coil may receive the resultant RF signal from the excited nuclei. The coil is designed as a receive-only coil for high resolution MR examination of breast.

The coil housing features a curved surface for better adaption to the anatomical region of interest. The coil is receive-only (Rx) and consists of 16 independent single loop coil elements with integrated low noise preamplifiers and a connector to the GE 1.5 T MR Systems or the GE 3.0 T MR Systems. The coil is fixed tuned and matched to the typical load of a breast at the Larmor frequency of 1H at 1.5 T (63.9 MHz) or 3.0 T (127.7 MHz) respectively. Decoupling circuits are integrated in each single loop element providing a decoupling from the Body Coil of the MR System during transmission of the RF excitation pulse. The coil provides both, unilateral and bilateral images (Left, Right and Both) of the anatomy of interest.

Equivalency Information

RAPID Biomedical believes that the Subject Device is substantially equivalent to the cleared Predicate Device which is described in the following submission.

Predicate Device Name	Clearance Number	Date
16ch AI Breast Coil 1.5T and 16ch AI Breast Coil 3T	K083255	2008-11-21

Summary of Technological Characteristics of the Subject Device as compared with the Predicate Device

The proposed labelling is adjusted compared to the predicate device with respect to differing MR Systems, changes in the currently applicable standards and for better usability.

Overall, the indications for use, the intended use and the coil technology and safety are substantially equivalent.

General Safety and Effectiveness Concerns

The safety and performance parameters according to the FDA Guidance Document *"Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, issued on Nov. 18, 2016"* are unaffected by the modifications described within this notification.

Nonclinical Tests

Nonclinical tests were performed on a loading phantom to evaluate the subject device concerning applicable imaging parameters Signal to Noise Ratio (SNR) and Image Uniformity. Test were conducted following NEMA Standards. Test results show an enhanced SNR performance of the subject device, while determined Image Uniformity compares well to the results from the predicate device.

The subject device is conforming to:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC)). FDA Recognition number: #19-4
- IEC 60601-2-33 Ed. 3.1:2013, medical electrical equipment - part 2-33: particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. (Radiology). FDA Recognition number: #12-271
- NEMA Standards Publication MS 6-2008 (R2014) - Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging. FDA Recognition number: #12-195
- NEMA Standards Publication MS 9-2008 (R2014) - Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images. FDA Recognition number: #12-288

All safety tests were performed on GE MR Systems. The test results are approved by GE for proving the full system compatibility.

Clinical Tests

Clinical tests were performed on volunteers in order to check image quality in vivo. Typical sequences for diagnosis were applied (Vibrant, DWI, CUBE T2-flex, FSE T2 with Aspir, FSPGR-T1) with standard scan parameters and image orientations (axial and sagittal). Clinical test show that the subject device provides adequate image quality (SNR, penetration depth, contrast, resolution and robustness against artifacts) as well as scan time and patient comfort are good.

Sample clinical images (Dicoms) are provided as part of the discussion of the clinical tests submitted.

Conclusion as to Substantial Equivalence

Testing was performed to support this claim of substantial equivalence and to show that the modifications do not raise any new questions pertaining to safety and effectiveness.

The modifications did not affect the Indications for Use, the Intended Use and did not alter the Fundamental Scientific Technology.

RAPID Biomedical therefore believes the subject devices and the Predicate Devices to be substantially equivalent (SE).

Rimpar, 2018-11-15

Signature:

Name: Christian Zimmermann

(Official Correspondent)