January 31, 2020

RAPID Biomedical GmbH
℅ Mr. Christian Zimmermann
Quality Management & Official Correspondent
Kettelerstrasse 3-11
97222 Rimpar, Bavaria
GERMANY

Re: K191539
Trade/Device Name: 1.5T Endorectal Coil, O-HLE-015-01899 and O-HLE-015-01946, 3.0T Endorectal Coil, O-HLE-030-01900; ER Coil Support, ZUB-01955
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: September 17, 2019
Received: December 23, 2019

Dear Mr. 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/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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191539

Device Name

Indications for Use *(Describe)*

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.

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510(k) Summary K191539

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: 2019-06-03

1. **Manufacturer**
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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: 1.5T Endorectal Coil and 3.0T Endorectal Coil

Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use

The Endorectal Coil is indicated for use as diagnostic device extension 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, displaying the internal structure of the prostate.

These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Device Description

The Endorectal Coil (1.5T Endorectal Coil O-HLE-015-01899, 1.5T Endorectal Coil O-HLE-015-01946, 3.0T Endorectal Coil O-HLE-030-01900 and ER Coil Support ZUB-01955) 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 reusable receive-only coil for high resolution MR examination of the prostate.

The coil housing is minimum sized and drop-shaped for better patient comfort. It features a flat top to minimize the distance of the inside receive coil electronics to the prostate. The coil is receive-only (Rx) and consists of a single loop coil element with an integrated low noise preamplifier and a connector to the GE 1.5 T MR-System or GE 3.0 T MR-System. The coil is fixed tuned and matched to the typical loading condition of a prostate examination 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 the single loop element providing a decoupling from the Body Coil of the MR System during transmission of the RF excitation pulse.

It is recommended to employ an Endorectal Coil Model in combination with the additional available ER Coil Support. The ER Coil Support is designed for use with any Endorectal Coil Model (1.5T Endorectal Coil O-HLE-015-01899, 1.5T Endorectal Coil O-HLE-015-01946 and 3.0T Endorectal Coil O-HLE-030-01900). It supports stabilizing the Endorectal Coil in any position required by each individual endorectal MR examination. The ER Coil Support features a collet for acceptance of the Endorectal Coil. The Endorectal Coil is fixated inside the collet by tightening of a knurled screw. It offers five degrees of freedom to align the position of the collet with the required spatial position of the Endorectal Coil housing. Two additional knurled screws allow the lock the ER Coil Support in the desired alignment.

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	Clearance Number	Date
MEDRAD 3.0T eCoil Imaging System	K060401	03/15/2006
MEDRAD 1.5T Pelvic Imaging System Interface Device	K053042	11/17/2005

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 for SUBJECT DEVICE according to the FDA Guidance Document *"Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, issued on Nov. 18, 2016"* are equivalent or better than for the PREDICATE DEVICE.

Nonclinical Tests

Nonclinical tests were performed on a phantom to evaluate the SUBJECT DEVICE concerning applicable imaging parameters Signal to Noise Ratio (SNR) and Image Uniformity. Tests 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. 3.2 b:2015: Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. FDA Recognition number: #12-295.
- 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.

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 in order to check image quality in vivo. Typical sequences for diagnosis were applied (T2 weighted, Propeller, DWI) with standard scan parameters and image orientations (axial and sagittal). Clinical tests 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 in DICOM format 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, 2019-06-04

Signature:

Name: Christian Zimmermann

(Quality Management & Official Correspondent)