RAPID Biomedical GmbH
℅ Marius Berthel
Regulatory Affairs Specialist
Kettelerstr. 3-11
Rimpar, Bavaria 97222
Germany

February 1, 2023

Re: K213480
Trade/Device Name: 31P/1H Head Coil, 23Na/1H Head Coil, 13C/1H Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: January 2, 2023
Received: January 3, 2023

Dear Marius Berthel:

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,

NINGZHI LI

Digitally signed by NINGZHI LI
Date: 2023.02.01 13:14:38 -05'00'

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213480

Device Name
31P/1H Head Coil, 23Na/1H Head Coil, 13C/1H Head Coil

Indications for Use *(Describe)*
The Head Coil is indicated for use as diagnostic device extension for a Philips, Siemens or GE 3.0 T MR system to provide cross-sectional 1H and/or any X nucleus images, spectroscopic images and/or spectra in any orientation of the internal structure of the head of the patient. 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: 2022-03-22

1. **Manufacturer**
   RAPID Biomedical GmbH
   Kettelerstrasse 3-11
   97222 Rimpar, Bavaria, Germany
   FEI: 3005049692
2. **Distributed by**
   Siemens Medical Solutions USA, Inc.
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   Malvern, PA 19355, USA
   FEI: 2240869
   Philips Medical Systems Nederland BV
   Veenpluis 4-6
   5684 PC Best, Netherlands
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   Waukesha, WI 53188
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3. **Contact Person**
   Mr. Marius Berthel
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   email: marius.berthel@rapidbiomed.de
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: 31P/1H Head Coil, 23Na/1H Head Coil, 13C/1H Head Coil
Proprietary Name: Dual Tuned Head Coil 3T

Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use

The Head Coil is indicated for use as diagnostic device extension for a Philips, Siemens or GE 3.0 T MR system to provide cross-sectional 1H and/or any X nucleus images, spectroscopic images and/or spectra in any orientation of the internal structure of the head of the patient.

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

Intended Population

Adolescent (from 12 years to 18 years of age)

Transitional Adolescent A (18 through 21 years of age)

Transitional Adolescent B (18 through 21 years of age)

Adults (greater than 21 years of age)

Device Description

The Head Coil is used in Magnetic Resonance Imaging and Spectroscopy (MRI, MRS). The Head Coil has been designed to be used on Siemens, Philips or GE 3.0 T MR systems. The Head Coil is a transmit/receive coil to excite and detect radiofrequency (RF) signals of hydrogen (1H) nuclei in combination with either phosphorus (31P), carbon (13C) or sodium (23 Na) nuclei. Excitation of the nuclei is achieved by applying an RF magnetic field. The detected signal is an RF voltage being induced in the Head Coil by the nuclei observed. The Head Coil mainly offers passive antenna technology for linking the MR system to the patient (and reverse).

Equivalency Information

RAPID Biomedical believes that the *SUBJECT DEVICE* is substantially equivalent to the cleared *PREDICATE DEVICE* which is described in the following submission:

DUAL TUNED HEAD COIL 3T	Clearance Number	Date
31P/1H Head Coil 3T 23Na/1H Head Coil 3T 13C/1H Head Coil 3T	K102748	2011-05-13

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* with regard to the applicable imaging parameters Signal to Noise Ratio (SNR) and Image Uniformity. Tests were conducted following NEMA Standards. Moreover and following the principle of reciprocity the transmit efficiency (which is applicable to transmit / receive coils) was compared between *SUBJECT DEVICE* and *PREDICATE DEVICE*. Test results show an equivalent or better SNR and Image Uniformity performance of the *SUBJECT DEVICE*.

ESD-Tests have been performed and successfully passed according to the requirements of IEC 60601-2-33 Ed. 3.2 b:2015, Chapter 202.8.101.

The *SUBJECT DEVICE* is conforming to:

- Recognition number 19-4: 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)).
- Recognition number 12-295: 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.

- Recognition Number 12-188: NEMA MS 1-2008 (R2020) - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- Recognition Number 12-187: NEMA MS 3-2008 (R2020) - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images

All relevant safety tests were performed on the workbench and, where applicable and necessary, on Siemens, Philips and GE 3.0T MR systems.

Clinical Images

Clinical images were acquired in order to check image quality *in vivo*. Gradient and spin echo sequences which are typical for diagnosis were applied with standard scan parameters and image orientations (axial, sagittal and coronal). These 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 that patient comfort are good.

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 DEVICE* and the *PREDICATE DEVICE* to be Substantially Equivalent (SE).

Rimpar, 2022-12-21

Signature:

Name: Dr. Titus Lanz

(Manager Development)