DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Rapid Biomedical Gmbh
Christian Zimmermann
Official Correspondent
Kettelerstr. 3-11
Rimpar, 97222 DE

March 21, 2018

Re: k163661
Trade/Device Name: P-140-flex Coil, Na-140-flex Coil, C-140-flex Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: February 12, 2018
Received: February 12, 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K163661

Device Name
P-140-Flex Coil, Na-140-Flex Coil, C-140-Flex Coil

Indications for Use *(Describe)*
The P-140-Flex Coil, Na-140-Flex Coil and C-140-Flex Coil are indicated for use as diagnostic device extensions for Philips 3.0 T MR Systems to produce cross-sectional spectroscopy images and/or spectra in any orientation of the internal structure of the whole body, e.g. of the calf, liver or heart. 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: 2017-06-30

**Manufacturer**

RAPID Biomedical GmbH

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FDA FEI: 3005049692

**Designed and Manufactured for**

Philips Medical Systems Nederland BV

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FDA FEI: 3003768277

**Contact Person**

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## *Classification and Device Names*

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: P-140-Flex Coil, Na-140-Flex Coil or C-140-Flex Coil

## Indications for Use

The P-140-Flex Coil, Na-140-Flex Coil and C-140-Flex Coil are indicated for use as diagnostic device extensions for Philips 3.0 T MR Systems to produce cross-sectional spectroscopy images and/or spectra in any orientation of the internal structure of the whole body, e.g. of the calf, liver or heart. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

## Device Description

The P-140-Flex Coil, Na-140-Flex Coil and C-140-Flex Coil are single tuned surface type transmit and receive coils for usage in magnetic resonance systems, the operating frequency and interface being adapted for usage on Philips 3.0 T MR Systems. The coils are for transmit and receive (T/R) and provide the required magnetic RF field for excitation of the spins and receive the MR signal of 31P, 23Na or 13C spins. This is used for axial, sagittal, coronal and oblique imaging, spectroscopic imaging and/or spectroscopy, which display the internal structure and/or function of the human anatomy, e.g. of the calf, liver or heart.The coils are optimized for local examinations of human subjects. The housing is flexible for better adaption to the anatomical region of interest. The coils consist of a single loop (linear) with a diameter of 14 cm, RF routing (T/R switch), a low noise preamplifier and a connector to the Philips 3.0 T MR Systems. The coils are fixed tuned and matched to the typical load of human tissue at the Larmor frequency of 31P (51.7 MHz), 23Na (33.8 MHz) or 13C (32.1 MHz) at 3.0 T. There is no detuning or switching mechanism in the loops. The loops are tuned permanently to the working frequencies of 31P, 23Na or 13C while being decoupled from the 1H body coil at the 1H frequency.

## Equivalency Information

RAPID Biomedical believes that the subject devices are substantially equivalent to the Philips Phosphorous Spectroscopy Surface Coil P-140 which is an extension of the cleared Philips Magnetic Resonance Diagnostic Devices (MRDD) which are described in the submission:

| Predicate Device Name | Clearance Number | Date |
|---|---|---|
| ACHIEVA family | K043147 | 2005-02-15 |

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

The subject device (P-140-Flex Coil, Na-140-Flex Coil and C-140-Flex Coil) and the predicate device (Philips P-140 Coil) are made for the usage on Philips 3.0T MR Systems as transmit/receive coils. The Philips 3.0 T MR Systems allow 31P, 23Na and 13C spectroscopy imaging and spectroscopy, including simultaneous 1H MR examinations and are capable of driving the subject device as described in the indications for use. Compared to the predicate device, the subject device yields flexible housing parts for better fitting the anatomy of the patient and offering better patient comfort. This gain in performance does not yield detrimental effects on the safety, reliability or other performance topics as compared to the predicate device. The active coil diameter of 14 cm of the subject device is exactly the same as the diameter of the predicate device. Subject device and predicate device do not offer a 1H channel for direct 1H MR examinations. These 1H examinations are provided by using the standard 1H body coil of the Philips 3.0 T MR System. The subject device is fixed tuned and matched while the predicate device has to be tuned and matched manually per patient.
Overall, the subject device and the predicate device share the substantial coil technology. Improvements in performance rectify the modifications in design while the intended use, the indication for use and safety stay substantially equivalent.

## General Safety and Effectiveness

The safety and performance parameters specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this submission.

The subject devices are conforming to:

- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
    - with National Differences for United States (US), ANSI/AAMI ES60601-1: 2005 / A2:2010 and
    - Canada (CA), CAN/CSA-C22.2 No. 60601-1:08
- IEC 60601-2-33: 2010 (Third Edition) + A1: 2013 for use in conjunction with IEC 60601-1:2005 + A1: 2012.

This will assure that the performance is to be considered safe and effective when used with the Philips 3.0 T MR Systems.

## 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 and did not alter the Fundamental Scientific Technology.**

**RAPID Biomedical therefore believes the subject devices and the predicate device to be substantially equivalent (SE).**

Rimpar, 2017-06-30

Signature:

Name: Christian Zimmermann

(Quality Management & Official Correspondent)