K102348
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Section 8 510(k) Summary

DEC 2 2 2010

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

I. General Information

Date of summary preparation: December 22, 2010

Manufacturer

Rapid Biomedical GmbH
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Kettelerstrasse 3-11
D-97222 Rimpar, Germany
Germany

Registration number: 3005049692

Importer/Distributor

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Columbus, Ohio 43219-3565
USA

Owner/operator number: 10033421

Contact Person

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II. 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 Name(s):	31P/1H Dual Tuned Surface Coil 3 T
	23Na/1H Dual Tuned Surface Coil 3 T
	13C/1H Dual Tuned Surface Coil 3 T

III. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The Dual Tuned Surface Coils 3T are surface type transmit/receive coils dual tuned on 1H (proton) and either 31P (phosphorus), 23Na (sodium) or 13C (carbon) nuclei. The coils are indicated for use as a diagnostic imaging device accessory to Siemens MAGNETOM Trio, A Tim System 3T and MAGNETOM Verio 3T magnetic resonance diagnostic devices to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Device Description

The Dual Tuned Surface Coils 3 T are transmit/receive surface coils to detect radiofrequency (RF) signals of hydrogen (1H) nuclei in combination with either phosphorus (31P), carbon (13C) or sodium (23Na) nuclei. Each coil consists of two single concentric loops, one of which is always tuned to the proton frequency, the other being tuned to either phosphorus-31P, carbon-13C or sodium-23Na frequency. Additional components are housed in a separate interface housing box.

Equivalency Information

Rapid Biomedical believes that the Dual Tuned Surface Coils 3 T are substantially equivalent to the cleared 31P/IH heart/liver coil by Siemens Healthcare (formerly Siemens Medical Solutions) which is described in the following submission:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Medical Solutions 31P/IH heart/liver coil included in *syngo* MR 2002B	K020991	Jun 13th, 2002

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

In contrast to the predicate device, the Dual Tuned Surface Coils 3 T are designed for a field strength of 3 T. While the predicate device was only available as 31P/1H coil, the new devices are also available as 23Na/1H and 13C/1H coils. Although the predicate coil is designed for non-invasive in vivo detection of 31P-metabolites instead of the additional 13C and 23Na metabolites detectable with the coils described in this submission, we believe that they are substantially equivalent Magnetic Resonance Specialty Coils for spectroscopy of nuclei other than protons. Numerous publications by researchers worldwide support the usefulness of 13C and 23Na spectroscopy. No risks different to standard MR occur for the patient during these investigations.

General Safety and Effectiveness Concerns

The following safety and performance parameters:

[Safety]

- Maximum Static Field
- Rate of Change of Magnetic Field
- Acoustic Noise Level

[Performance-Imaging]

- Geometric Distortion
- High Contrast Spatial Resolution

[Performance-Spectroscopy]

- Spatial Localization Accuracy
- Peak Assignment Accuracy
- Solvent Suppression

specified by the FDA Guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

The following parameters were considered for the new Dual Tuned Surface Coils 3 T:

[Safety]

- Biocompatibility
- RF Power Deposition

[Performance-Imaging]

- Signal to Noise Ratio
- Image Uniformity
- Slice Profile, Thickness and Gap

[Performance-Spectroscopy]

- Spectral Resolution
- Signal to Noise Ratio
- Decoupling

The new devices conform to IEC 60601-1 and IEC 60601-2-33, 2nd edition. All safety tests are performed on the Siemens MAGNETOM Trio a Tim System. This is the

most critical engine for safety and performance of the Siemens MAGNETOM 3T series. Passing these tests gives the Siemens approval for the complete MAGNETOM 3T series.

No new materials coming in contact with patients were used for the new Dual Tuned Surface Coils 3 T compared to the predicate device. Therefore no biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests according to NEMA MS 6-2008 as well as slice profile tests according to NEMA MS 5-2003 were performed for the new Dual Tuned Surface Coils 3 T and the results presented in this submission show that they are equivalent with the predicate devices.

Furthermore, spectroscopic tests on SNR, spectral resolution and decoupling were carried out.

Conclusion as to Substantial Equivalence

Laboratory testing was performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Armin Purea
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GERMANY 97222

DEC 2 2 2010

Re: K102348
Trade Name: 31P/1H Dual Tuned Surface Coil; 13C/1H Dual Tuned Surface Coil 3T; 23Na/1H Dual Tuned Surface Coil 3T
Regulation Number: 21 CFR § 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 29, 2010
Received: December 1, 2010

Dear Mr. Purea:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 3 Indications for Use Statement

Indications for Use

DEC 2 2 2010

510(k) Number: K102348

Device Name: Dual Tuned Surface Coils 3T

Indications for Use:

The Dual Tuned Surface Coils 3T are surface type transmit/receive coils dual tuned on 1H (proton) and either 31P (phosphorus), 23Na (sodium) or 13C (carbon) nuclei. The coils are indicated for use as a diagnostic imaging device accessory to Siemens MAGNETOM Trio, A Tim System 3T and MAGNETOM Verio 3T magnetic resonance diagnostic devices to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

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