K083255

NOV 21 2008

Section 8 510(k) Summary

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

I. General Information

Date of summary preparation: October 08, 2008

Manufacturer
Rapid Biomedical GmbH
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D-97222 Rimpar, Germany
Germany

Registration number: 3005049692

Importer/Distributor
Siemens AG
Healthcare Sector
Henkestrasse 127
D-91052 Erlangen, Germany
Germany

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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:	16 Ch AI Breast Coil 1.5 T 16 Ch AI Breast Coil 3 T

III. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The 16 Ch AI Breast Coil 1.5 T and the 16 Ch AI Breast Coil 3 T are indicated for use as a diagnostic imaging device accessory to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that displays the internal structure of the breast.

Device Description

The 16 Ch AI Breast Coil 1.5 T and the 16 Ch AI Breast Coil 3 T are receive only MR coils for imaging the human breast. Both coils consist of 16 coil elements. Two housing halves each contain eight independent coil elements. Seven of each are arranged in a cylindrical geometry while one element is positioned in a horizontal plane at top of the cylinder faced outwards.

Equivalency Information

Rapid Biomedical believes that the 16 Ch AI Breast Coil 1.5 T and 3 T is substantially equivalent to the cleared CP Breast Array Coil for MAGNETOM Harmony and Symphony systems and the described in the following submission:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
CP BREAST ARRAY COIL	K973630	12/05/1997

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

In contrast to the predicate device, the 16 Ch AI Breast Coils 1.5 T and 3 T consist of 16 coil elements as opposed to 4. Furthermore, the 16 Ch AI Breast Coil 3 T is designed for a field strength of 3 T. We believe, however, that both coils are substantially equivalent to the predicate device.

General Safety and Effectiveness Concerns

The following safety and performance parameters:

[Safety]
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance-Imaging]
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

[Performance-Spectroscopy]
- Spatial Localization Accuracy
- Peak Assignment Accuracy
- Solvent Suppression
- Decoupling

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 16 Ch AI Breast Coil Kit 1.5 T and 3 T:

[Safety]
- Biocompatibility

[Performance-Imaging]
- Signal to Noise Ratio
- Image Uniformity

[Performance-Spectroscopy]
- Spectral Resolution
- Signal to Noise Ratio

No new materials were used for the new 16 Ch AI Breast Coil Kit 1.5 T and 3 T compared to the predicate device. Therefore no biocompatibility tests were performed. Signal to Noise Ratio (SNR) and image uniformity tests according to IEC 62464-1 were performed for the new 16 Ch AI Breast Coil Kit 1.5 T and 3 T and the results presented in this submission show that they are equivalent with the predicate devices. Furthermore, spectroscopic tests on SNR and spectral resolution 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
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

RAPID Biomedical GmbH
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K083255
Trade/Device Name: 16 Ch AI Breast Coil 1.5 T and 16 Ch AI Breast Coil 3 T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 31, 2008
Received: November 4, 2008

Dear Mr. Borsai:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 2 Indications for Use Statement

Indications for Use

510(k) Number (if known) K083255

Device Name: 16 Ch AI Breast Coil 1.5 T and 16 Ch AI Breast Coil 3 T

Indications for Use:

The 16 Ch AI Breast Coil 1.5 T and the 16 Ch AI Breast Coil 3 T are indicated for use as a diagnostic imaging device accessory to produce transverse, sagittal, coronal and oblique images, spectroscopic images and/or spectra, and that displays the internal structure of the breast.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083255