K112112

AUG 25 2011

7 510(k) Summary

Refer to Appendix 5

510(k) Summary of Safety and Effectiveness for: Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems

I. Manufacturer

Sentinelle Medical Inc.
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Canada M5V 3B1

II. Contact Person

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Director, Regulatory and Quality
Tel: (647) 258-3607
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III. Product Name/Classification Name

Product Name:	Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems
Common Name:	Sentinelle Breast Coil for Siemens MRI Systems
Classification Name:	Magnetic Resonance Imaging Accessory Class II as described in CFR 21 892.1075
Product Code:	MOS

IV. Date Prepared

July 15, 2011

V. Device Description

The **Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems** is a receive-only MRI imaging coil and interventional system for breast anatomy. The system consists of a tabletop which supports the patient and imaging coils which provide a means of enabling interventional device guidance.

The tabletop, like other breast coils provides an aperture to admit the breasts and provides the physician access to the breast(s). This aperture enables the guidance of interventional devices (such as biopsy needles), when performing a biopsy.

The tabletop's compression system facilitates immobilization of the breast for imaging and interventional procedures and serves to hold the individual imaging coils in proximity to the breast(s).

Compression plates (also referred to as immobilization plates) provided with the system are held in frames, which may be positioned in the left-right and anterior-posterior directions and fixed in place to gently immobilize one or both breasts for interventional procedures.

When performing a stereotactic interventional procedure (such as biopsy or wire localization), one or more compression plates may be interchanged for a sterile, single use, disposable fenestrated plate (also referred to as biopsy grid) cleared under FDA 510(k) Number: K060873. The biopsy grid contains apertures that permit the physician to access the breast for intervention, while minimizing tissue motion.

When performing biopsy and/or imaging of a single breast, the system may be used with two compression plates immobilizing that breast. The contralateral breast support prevents the contralateral breast from interfering with medial-approach interventions.

When imaging both breasts, a medial coil element is used between the breasts in conjunction with two lateral coils.

The tabletop's receive-only coil system acts to passively collect RF emissions from the nuclei excited by the MRI. The function of the tabletop is substantially equivalent

to predicate devices used for breast MRI imaging and intervention, including our legally marketed device [510(K) Number: K100113].

The Sentinelle phased array breast coil set consists of 2, 10 or 16 RF coil elements in a phased array design. The coil elements and electronics are enclosed in a rigid housing that is resistant to fluid ingress and is fire retardant. The coils are positioned close to the patient's breast during imaging. This receive-only coil is designed to give an improved signal-to-noise ratio, image resolution and image acquisition over that of a standard body coil.

The Sentinelle 16Ch Coil Array for Siemens 1.5/3T MRI Systems, receive-only coil provides the following benefits:

- an increase in the Signal-to-Noise Ratio improving image detail in the breast including axilla and chest wall regions
- a decrease in imaging acquisition time resulting from enhanced parallel imaging capability
- allows the user to perform advanced pulse sequences including (but not limited to) diffusion weighted imaging, diffusion tensor imaging and spectroscopy imaging
- allows for the use of IPAT squared and acceleration factors up to 4 in L-R and 2 in S-I and A-P direction in a diagnostic imaging state

This system is compatible with:

- ☐ Siemens 16 Channel, 1.5T MRI Scanners (Siemens MAGNETOM Espree)
- ☐ Siemens 16 Channel, 3T MRI Scanners (Siemens MAGNETOM TRIO)

A full description of the system in form and function and the accompanying technical drawings were provided in the Traditional 510(K) cleared in April 2006 under FDA 510(k) Number: K060873 and Special 510(k) cleared in April 2010 under FDA 510(k) Number: K100113.

A copy of the Operator's Guide (User Manual) which details the proposed labeling (operating instructions, cautions, warnings, and indications for use) can be found in Appendix 9.

VI. Intended Use

The Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5T or 3T MRI Systems is an open, receive only breast coil designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. It is intended for routine diagnostic imaging and intervention of the breast and axillary region. When used with a biopsy grid, the device permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

*Note: The intended use of this modified device, as described in its labeling has not changed as a result of the modifications.

VII. Substantial Equivalence

The Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems is substantially equivalent to our legally marketed device "Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE Signa™ 1.5/3T Systems cleared under 510(k) Number: K100113.

Table 2:

Device Name:	**Vanguard Breast MRI Auxiliary Table with 8/16 Channel Coil Array for GE 1.5/3T MRI Systems**
Manufacturer:	Sentinelle Medical Inc.
510(k) Number:	K100113
Decision Date:	April 22, 2010
Decision:	Substantially Equivalent

Table 3 lists the technological characteristics, as derived from the Indications for Use and the Device Description of the proposed device with the legally marketed device Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE Signa™ 1.5/3T MRI Systems.

The device labeling includes the Operator's Guide (User Manual) [Appendix 9] including indications for use, cautions, warnings, contraindications and instructions. This information assures safe and effective use of the device.

Table 3: Technological Characteristics

Comparison of Sentinelle Breast MRI Auxiliary Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems with Vanguard Breast MRI Auxiliary Table with 8/16 Channel Coil Array for GE Signa™ 1.5/3T MRI Systems

Predicate: Vanguard Breast MRI Auxiliary Table with 8/16 Channel Coil Array for GE 1.5/3T MRI Systems K100113	**Current Submission:** Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems
Indications for Use: Provides magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with the disposable sterile plate this device permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.	**Indications for Use:** Provides magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with the disposable sterile plate this device permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.
Design and Technology: The device supports a patient in a prone position, with receive-only antennas surrounding the breast. Compression plates supported by the device are used to immobilize the breast in the opening provided. Only non-ferrous materials are used in the construction of the device. Detailed aspects of technology presented in sections below	**Design and Technology:** The device supports a patient in a prone position, with receive-only antennas surrounding the breast. Compression plates supported by the device are used to immobilize the breast in the opening provided. Only non-ferrous materials are used in the construction of the device. Detailed aspects of technology presented in sections below
Coil Enclosure and compression plate material: Flame retardant Polycarbonate plastic, Acetal Resin and Polyurethane. Patient contact materials have been evaluated for biocompatibility.	**Coil Enclosure and compression plate material:** Flame retardant Polycarbonate plastic, Acetal Resin and Polyurethane. Patient contact materials have been evaluated for biocompatibility.
Technology - Coil Design: - 16 loop phased array receive only coil design. - 10 loop phased array receive only coil design - 2 loop phased array receive only coil design	**Technology - Coil Design:** - 16 loop phased array receive only coil design. - 10 loop phased array receive only coil design - 2 loop phased array receive only coil design

Technology - Decoupling: Active PIN Diode switching blocking circuitry. Passive Blocking Circuitry.	**Technology - Decoupling:** Active PIN Diode switching blocking circuitry. Passive Blocking Circuitry.
Technology - Prevention of RF Burns: Cables can not be looped.	**Technology - Prevention of RF Burns:** Cables can not be looped.
Technology - Radio Frequency Absorption: Coil is a receive-only coil and does not transmit RF power. Power deposition is limited by the SAR program of the MRI magnet.	**Technology - Radio Frequency Absorption:** Coil is a receive-only coil and does not transmit RF power. Power deposition is limited by the SAR program of the MRI magnet.
Technology - Formation of Resonant Loop: Decoupling isolates the coil elements from RF fields during RF transmission.	**Technology - Formation of Resonant Loop:** Decoupling isolates the coil elements from RF fields during RF transmission.
Performance Testing: Performance was determined according to NEMA standards for MRI Coils as applicable to phased array coils.	**Performance Testing:** Performance was determined according to NEMA standards for MRI Coils as applicable to phased array coils.
Specifications - Mode of operation, Frequency, Field Strength : For 3 Tesla variants: Receive-only, center frequency ranging from 123.1 MHz to 127.3 MHz (Factory Set), 3 Tesla, Bilateral and unilateral applications, Medial, Lateral and anterior access.	**Specifications - Mode of operation, Frequency, Field Strength : For 3 Tesla variants:** Receive-only, center frequency ranging from 122.6 MHz to 124.2 MHz (Factory Set), 3 Tesla, Bilateral and unilateral applications, Medial, Lateral and anterior access.
Compatibility: This system is for use with GE Discovery MR 750 3.0T, GE Signa HDxt 3.0T, General Electric Discovery MR450 1.5T, General Electric Optima MR450w 1.5T	**Compatibility:** This system is for use with Siemens MAGNETOM Espree & Siemens TRIO MRI Scanners
Table Specifications: For use with products specified in the compatibility section. Max table weight verified per MR requirements. Relative table motion is controlled by MR system.	**Table Specifications:** For use with products specified in the compatibility section. Max table weight verified per MR requirements. Relative table motion is controlled by MR system.

VIII: Testing and Performance Data

Testing for the Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems was performed to ensure that functional requirements have been met, and that core functions execute as expected.

The following tests were performed on the proposed device and the verification/validation results are contained in Appendix 8.

Table 4: Product Under Test – Sentinelle 16CH Coil Array for 1.5T Scanners

Test Identifier	Test Reference
DHM-00932	Mechanical Safety Testing Summary
SMI-1093	Risk Management Report for Sentinelle Vanguard 16Ch Breast System for Siemens MR Platform (1.5T and 3.0T)
SMI-1839	Mechanical FMEA: 16 Channel for Siemens
SMI-0337	FMEA Siemens Tabletop
RSK-00309	Electrical FMEA: 16CH for Siemens 1.5T and 3T
TR-00484	SNR Evaluation – Siemens 1.5T 16CH System
TR-00483	Siemens – gMap 16CH 1.5T
VER-04170	Heating and Performance Output Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04171	Passive Detuning Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04172	Field Distortions Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04173	RF Noise Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04174	Switch-Over Tx-Rx for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04175	MR Signal from Housing for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04176	Body Scout 2 for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04177	Body Scout 1 for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04178	Voltage Stability Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04179	Spike Noise Test for Siemens 1.5T, 16CH Breast Coil – 10CH Configuration
VER-04285	2CH Breast SEN QA 2011-04-27
VER-04287	10CH Breast SEN QA 2011-04-27
TR-0796	Passive Detuning during Transmit Phase for Siemens 1.5T, 16CH Breast Coil
TR-0804	Voltage Stability of Passive Decoupling for Siemens 1.5T, 16CH Breast Coil
TR-0781	Heating and Performance Output Test for Siemens 1.5T, 16CH Breast Coil

TR-0803	Body Scout 1 for Siemens 1.5T, 16CH Breast Coil
TR-0802	Body Scout 2 for Siemens 1.5T, 16CH Breast Coil
TR-0797	Measurement of Field Distortions for Siemens 1.5T, 16CH Breast Coil
TR-0798	Spike Noise Test for Siemens 1.5T, 16CH Breast Coil
TR-0799	Rf Noise Measurement for Siemens 1.5T, 16CH Breast Coil
TR-0800	Switch-over Tx-Rx for Siemens 1.5T, 16CH Breast Coil
TR-0801	MR Signal from Housing for Siemens 1.5T, 16CH Breast Coil
TR-00485	SNR Comparison between 8 CH and 16CH Systems
VAR-02350	Volunteer Imaging for Siemens 1.5T, 16CH Breast Coil
SMI-1789	Safety & Imaging Effectiveness: Siemens 1.5T 16CH

Table 5: Product Under Test – Sentinelle 16CH Coil Array for 3T Scanners

Test Identifier	Test Reference
VER-04180	Heating and Performance Output Test for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04181	Passive Detuning Test for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04182	Field Distortion Test for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04183	RF Noise Test for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04184	Switch-Over Tx-Rx for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04185	MR Signal from Housing for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04186	Body Scout 2 for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04187	Body Scout 1 for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04188	Voltage Stability Test for Siemens 3T, 16CH Breast Coil – 10CH Configuration
VER-04189	Spike Noise test: Siemens 16CH/3T – 10 CH Configuration
TR-0760	Passive Detuning during Transmit Phase for Siemens 3T, 16CH Breast Coil
TR-0761	Voltage Stability of Passive Decoupling for Siemens 3T, 16CH Breast Coil
TR-0769	Heating and Performance Output Test for Siemens 3T, 16CH Breast Coil
TR-0771	Body Scout 1 for Siemens 3T, 16CH Breast Coil
TR-0772	Body Scout 2 for Siemens 3T, 16CH Breast Coil

TR-0773	Measurement of Field Distortions for Siemens 3T, 16CH Breast Coil
TR-0774	Spike Noise Test for Siemens 3T, 16CH Breast Coil
TR-0775	RF Noise Measurement for Siemens 3T 16CH Breast Coil
TR-0776	Switch-over Tx-Rx for Siemens 3T, 16CH Breast Coil
TR-0777	MR Signal from Housing for Siemens 3T, 16CH Breast Coil
VER-04025	SNR Comparison between 8 and 16 Channel Systems at 3T for Siemens Breast Coil
VER-04216	gMap for Siemens 3T, 16CH Breast Coil
SMI-1371	Safety & Imaging Effectiveness: Siemens 16CH/3T
VAR-02363	Volunteer Imaging for Siemens 3T, 16CH Breast Coil

Testing was conducted in-house by trained testing personnel using phantoms or volunteers to obtain the functional and accuracy test results. The use of contrast agent was not used in obtaining the images. The completed test results demonstrated that no new safety and effectiveness issues were introduced. The completed tests were conducted to ensure that the changes to the proposed device did not introduce any new issues of safety or effectiveness from our legally cleared device – K100113.

The Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI System's indications for use are unchanged from our legally marketed predicate devices:

- Vanguard Breast MRI Auxiliary Table/Tabletop Coil with 8/16 Channel Coil Array for use with GE 1.5/3T MRI Scanners [K100113].

As such, the features and functionality provided by the Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems do not raise new concerns of safety or effectiveness.

Test Conclusion

Results of the verification activities for the Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5/3T MRI Systems verify that the system performed as intended, is safe and effective as our predicate device, and is substantially equivalent to our legally marketed device [K100113] .

Please refer to Appendix 8 for verification/validation results.

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

Ms. Joan Medley
Director, Quality & Regulatory
Sentinelle Medical, Inc.
555 Richmond Street West, Suite 800
Toronto, ON, M5V 3B1
CANADA

AUG 25 2011

Re: K112112
Trade/Device Name: Sentinelle Breast MRI Tabletop with 16Ch Coil Array for Siemens 1.5T/3T MRI Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 21, 2011
Received: July 25, 2011

Dear Ms. Medley:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication(s) For Use

510(k) Number:

Device Name: Sentinelle Breast MRI Tabletop with 16Ch Coil Array for Siemens 1.5T/3T MRI Systems

Indications for Use:

The Sentinelle Breast MRI tabletop with 16 Channel Coil Array for Siemens 1.5T/3T MRI Systems is designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images are interpreted by a trained physician. When used with a disposable sterile plate (biopsy grid), the device permits access to breast anatomy for biopsy and localization procedures.

Prescription Use (Part 21 CFR 801 Subpart D):	___√___	**AND/OR**	Over-The-Counter Use (Part 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 (ODE)

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

510K K112112