



Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INVIVO CORPORATION
C/O MARK JOB
REGULATORY TECHNOIOGY SERVICES LLC
1394 25TH STREET, NW
BUFFALO MN 55313

August 31, 2016

Re: K162001

Trade/Device Name: 1.5T and 3.0T 16CH GE Shoulder Coils

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: MOS

Dated: August 18, 2016

Received: August 19, 2016

Dear Mr. Job:

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 yours,



For

Robert Ochs, PhD
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162001

Device Name

1.5T and 3.0T 16CH GE Shoulder Coils

Indications for Use (Describe)

The 16 Channel Shoulder Coil is to be used in conjunction with Magnetic Resonance Scanners to produce diagnostic images of the shoulder that can be interpreted by a trained physician.

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.

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510(k) Summary

Submitted by: Invivo Corporation
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Establishment Name: Invivo Corporation

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Date Prepared: August 15, 2016

Trade Name: 1.5T and 3.0T 16 Ch GE Shoulder Coils

Common Name: Magnetic resonance diagnostic device

Classification Name: Coil, Magnetic Resonance, Specialty

Classification
Regulation Number: 892.1000

Classification: Class II

Classification Panel: Radiology

Product code: MOS

Device Description:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are designed for use with Magnetic Resonance Imaging (MRI) systems. The coil is designed to work in unison with the Body Coil of the MRI system, which will transmit the radio frequency (RF) signals, so that the coil may receive the resultant RF signal from the excited nuclei.

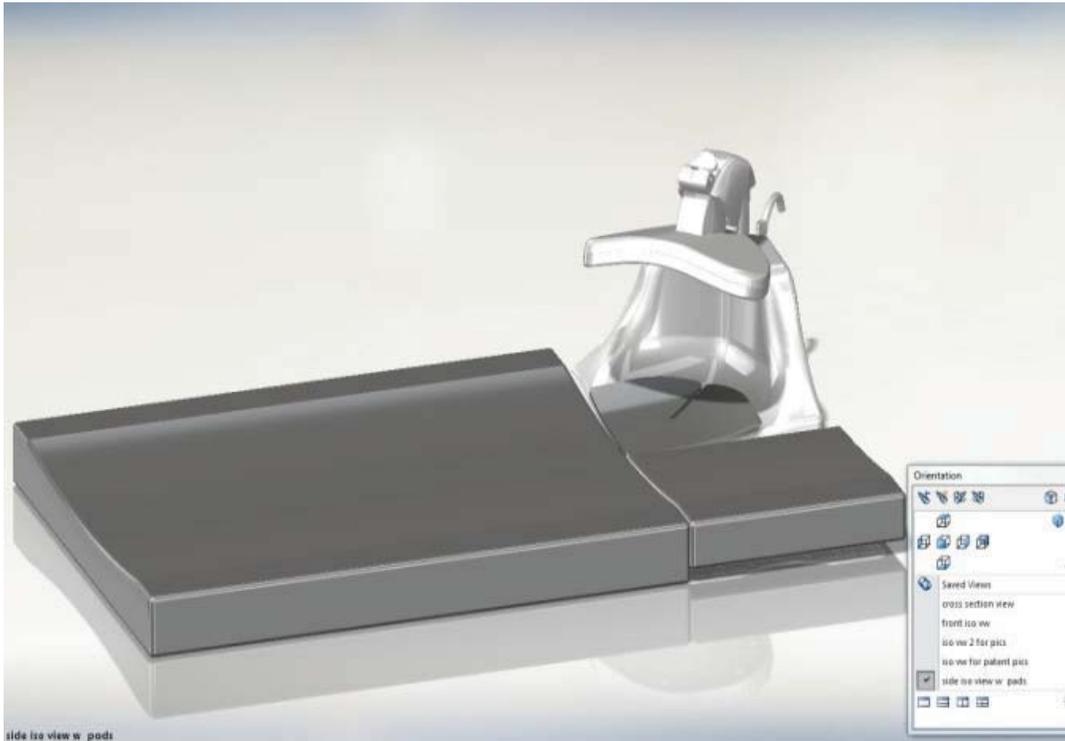
The proposed 1.5T and 3T 16Ch GE Shoulder Coils are identical to each other in construction with the exception that they are tuned to their respective frequencies and additional cable trap baluns are included on the 3T coil due to the shorter wavelengths associated with 3T. The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are designed as receive-only coils for high resolution diagnostic imaging of shoulder. The coils provide unilateral images (Left and Right) of the anatomy of interest.

Variations between the proposed 1.5T and 3T 16Ch GE Shoulder Coils and the predicate devices HRS-63-8 and HRS-127-8 Shoulder Array Coils include MR system compatibility and a 16-channel connection to the MRI system. Mechanical design changes include modifications to the connector to permit the 16-channel connection and the specified MR system compatibility. In addition, modifications to the housing from three-part adjustable to two-part adjustable design improves workflow as well as meets customer requirements.

Proposed changes to the device

- Coil housing material changed from Lexan 950 to Lexan 925A for ease of availability with no impact to device safety and effectiveness
- Coil pad coating changed from Guardian MPGX to Polyscan coating for ease of availability with no impact to device safety or effectiveness.
- Channel count was increased from 8 channels to 16 channels to meet the customer/market needs with no impact on device to safety and effectiveness.
- The overall coil dimensions were changed from 9.1" x 6.2" x 11.7" to 11" x 11" x 12.25" to accommodate more channels with no impact to device safety and effectiveness.
- The housing design was changed from a three-part adjustable housing to a two-part adjustable housing to improve ease of use and workflow with no impact to device safety and effectiveness.
- The GE OEM connector was updated from an ODU Bendix connector to an ODU P port connector to accommodate specified MRI Scanners with no impact to device safety and effectiveness.

Photograph:



System Compatibility:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are designed to be used with GE 1.5T and 3.0T MRI Systems respectively. The Models 1.5T and 3.0T 16 Ch GE Shoulder Coils are 16-channel receive-only coils. Models 1.5T and 3.0T 16 Ch GE Shoulder Coils include identical coils with slight variations between system connectors to allow compatibility with respective MRI Scanners.

The Model 1.5T 16 Ch GE Shoulder Coil will operate with the GE 1.5T MRI Scanners such as GE Signa Voyager MRI Scanner and the Model 3.0T 16 Ch GE Shoulder Coil will operate with GE 3.0T MRI Scanners such as GE Signa Pioneer MRI Scanner.

Patient Safety**Description of design that assures that the coil will remain decoupled:**

The coil incorporates a redundant decoupling strategy. Back-to-back fast recovery PIN diodes or Dual diodes are placed in series with an inductor across a capacitor. The inductor is tuned to shift the resonant frequency of the coil. During system transmitted pulses, a D.C. voltage is supplied to each channel of the array by the MRI system. This voltage drives the PIN diodes or Dual diodes they conduct, thus engaging the decoupling circuit. The coil resonant frequency then shifts away from the system resonant frequency. The coil therefore becomes a very poor receiver of RF energy at the system operating frequency during the transmit pulses.

In the event that the coil is placed in the magnet and the operator neglects to plug in the coil, the PIN diodes or Dual diodes function as a passive decoupling system. In this case, the decoupling takes place without the need for the voltage supplied by the MRI system.

Description of electrical isolation of the patient from the surface coil electrical conductors:

The electrical conductors are etched on FR4 printed circuit board. The circuit boards are encased in plastic housing. The plastic housing wall and/or foam is provided with a minimum of .10" thickness. At no time it is possible for the coil conductors to touch the patient.

The cable exits the coil superior to the patient's head to connect to the MRI system connector. The cables are of such a length to reach the MRI system coil part by running the cables away from patient. The cable is designed such that the cable is difficult to make the loop shape during use. The cables have insulation jackets and additional pad that increase separation of the cable if it did somehow become looped.

Indications for Use:

The 16 Channel Shoulder Coil is to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the shoulder that can be interpreted by a trained physician.

Predicate Device Information:

Predicate Device Name	Predicate 510(k) Submission Reference
HRS-63-8 and HRS-127-8 Shoulder Array Coils	K053017

Safety and Effectiveness:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils labeling contain instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via Invivo Risk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via the product development process, verification and validation testing and safety features provided by the MRI Scanners.

Technological Characteristics:

The technological characteristics of the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are exactly the same as the predicate devices HRS-63-8 and HRS-127-8 Shoulder Array Coils.

The technological characteristic of a receive-only radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest. This technological characteristic of the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils has not changed as compared to the technological characteristic of the predicate devices HRS-63-8 and HRS-127-8 Shoulder Array Coils.

Based on the information provided above, the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are considered substantially equivalent to the predicate devices HRS-63-8 and HRS-127-8 Shoulder Array Coils (K053017) in terms of technological characteristics.

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils utilize the same technological characteristic as the predicate devices. Both have similar design, intended use, patient safety features, housing materials, overall dimensions, and operating principals; and substantially equivalent in their performance and effectiveness for their intended uses.

Following is the comparison of technological characteristics between the Predicate and the proposed devices:

Table-01			
Comparison of the Technological Characteristics of the Predicate Device and the Proposed Device			
Device Features	Predicate Device K053017	Proposed Device	Comments
	HRS-63-8 and HRS-127-8 Shoulder Array Coils	1.5T and 3.0T 16 Ch GE Shoulder Coils	
Indications for Use	The coil is to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the shoulder that can be interpreted by a trained physician	The 16 Channel shoulder coil is to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the shoulder that can be interpreted by a trained physician	Similar, changed from a coil to specific 16 Channel Shoulder Coil. No Change in the Intended Use of the Coil
Coil Dimensions Length x Width x Height	9.1 x 6.2 x 11.70 inches	11 x 11 x 12.25 inches	The change in dimensions is to accommodate more channels. No impact to device safety and effectiveness.
Coil Frequency	63.87 MHz for 1.5T (or 127.73 MHz for 3.0T)	Identical	No Change
Coil Design	Receive-only Phased Array	Identical	No Change
Magnetic Field Orientation (B0)	Horizontal	Identical	No Change
Coil Geometry/ Housing Design	Three-part adjustable housing	Two-part adjustable housing	The change in housing design was to improve ease of use and workflow. No impact to device safety and effectiveness.
Housing Thickness	.10 inch insulation minimum	Identical	No Change
Decoupling Method	LC Tank Circuit	Identical	No Change

Table-01			
Comparison of the Technological Characteristics of the Predicate Device and the Proposed Device			
Device Features	Predicate Device K053017	Proposed Device	Comments
	HRS-63-8 and HRS-127-8 Shoulder Array Coils	1.5T and 3.0T 16 Ch GE Shoulder Coils	
Number of Channels/ Preamplifiers	8 channels / 8 preamplifiers	16 channels / 16 preamplifiers	The number of channels was increased to meet the customer and market needs. No impact to device safety and effectiveness.
Housing Material	Lexan 950	Lexan 925A	Both are similar materials and have been used in current products. No impact to device safety and effectiveness.
Base Pad	Urethane Foam with Guardian MPGX coating	Urethane Foam with Polyscan Coating	Both are similar materials and have been used in current products. No impact to device safety and effectiveness.
System Connector / Compatibility	ODU Bendix Connector for GE 1.5T/3.0T Scanner	ODU P Port Connector for GE 1.5T/3.0T Scanner	To be compatible with the specified MRI Scanners. No impact to device safety & effectiveness.

Non-Clinical testing and Performance Information:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils comply with the following international and FDA-recognized consensus standards:

- IEC 60601-1, 3rd edition
- IEC 60601-2-33, 3rd edition
- ISO 14971, 2nd edition
- ISO 10993-1
- Device specific draft guidance document, entitled “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices – July 14, 2015”

Bench performance testing includes both non-clinical testing and clinical demonstrations of the representative anatomic region (shoulder imaging) using FDA-cleared GE 1.5T and 3.0T scanners. The non-clinical testing characterizes the Signal-to-Noise Ratio (SNR), Image Uniformity and special purpose of the RF receive-only coil. The clinical demonstration DICOM images were reviewed by a clinical radiologist to confirm the image quality is adequate.

Non-clinical verification and validation test results demonstrate that the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils

- Comply with the device specifications, identified international and FDA-recognized consensus standards, and device specific guidance document entitled “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices”
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are as safe and effective as the predicate devices (K053017) in terms of safety and effectiveness.

Summary of Clinical Data:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils do not require clinical study since substantial equivalence to the predicate device was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Technological characteristic;
- Non-clinical performance testing, including Clinical Images review by Radiologist, and
- Device Safety and effectiveness

Conclusion:

The proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils are substantially equivalent to the predicate devices HRS-63-8 and HRS-127-8 Shoulder Array Coils (K053017). The substantial equivalency is based on design features, principles of operation, technological characteristic, indications for use, magnet system compatibility, clinical image review, and safety and effectiveness of the proposed devices. Additionally, the non-clinical performance (verification and validation) tests, which complied with the device specifications, and requirements specified in the international and FDA-recognized consensus standards demonstrated that the proposed 1.5T and 3.0T 16 Ch GE Shoulder Coils meet the acceptance criteria and are adequate for the established intended use. The electrical isolation methods, decoupling method and housing material are similar for the predicate and proposed devices.

The results of both non-clinical and device performance tests demonstrate that the proposed device is as safe, as effective, and performs as well as the predicate device.