GE Healthcare

NOV 25 2009

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: July 1st, 2009

Submitter: GE Healthcare Coils (USA Instruments Inc.)
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Device:

Trade Name: 3.0T 16 Channel Head Neck Spine Coil

Common/Usual Name: 3.0T HNS Coil

GE Healthcare

3.0T 16 Channel Head Neck Spine Coil
510(k) Premarket Notification

Classification Names: 21 CFR 892.1000

Product Code: 90MOS

Predicate Device(s): (1) 3.0T 16 Channel Brain/Spine (Neurovascular) Array Coil (K052916)

(2) 1.5T 16 Channel Brain/Spine Coil (K052612)

Device Description: The 3.0T Head Neck and Spine Coil is a receive-only 16-channel, 29-element coil designed for use with GE 3.0T MRI Systems. This rigid coil incorporates soft, flexible components that conform to patients' anatomy, accommodating various body contours while minimizing patient discomfort.

The Head, Neck and Spine Array (HNS) coil is comprised of 4 units: the Head/ Neck Unit (HNU), the Thoracic/ Lumbar unit (TLU) and the Neck Chest Unit (NCU) and Horseshoe.

The 3.0T HNS Coil has an array of 21 coil elements in the head neck units and 8 coil elements in the Spine Unit. Twelve coil elements cover the head region. Another four coil elements cover the lower neck and Brachial Plexus regions. Five coil elements cover the upper neck and the chest region. The Spine Unit has an array of 8 coil elements, which cover the thoracic and lumbar spine regions.

Intended Use: The GE 3.0T 16 Channel Head Neck Spine Coil is a receive-only RF coil designed for use with the 3.0T MRI system manufactured by GE Healthcare. The coil is intended for imaging of the brain; cervical, thoracic, and lumbar spines; as well as the soft tissues and vasculature of the head, neck, and upper chest. The nucleus excited is hydrogen.

Technology: The 3.0T 16 Channel Head Neck Spine Coil is a multi-element phased array RF Receive only coil with integrated preamplifiers. The coil design consists of RF chokes with switching diodes to provide decoupling which isolates the coil elements from RF fields during RF transmission. This coil is designed based on the same technology as the predicate devices.

Determination of Substantial Equivalence: The 3.0T 16 Channel Head Neck Spine Coil has the same indications for use as the predicate devices.

Comparison with 3.0T 16 Channel Brain/Spine Coil

The 3.0T 16 Channel Head Neck Spine Coil is a new device which is similar in design to the existing 3.0T 16 Channel Brain/Spine Coil (K052916).

Comparison with 1.5T 16 Channel Brain/Spine Coil

The 3.0T 16 Channel Head Neck Spine Coil is a new device which is similar to the existing 1.5T 16 Channel Brain/Spine Coil (K052621) with the primary difference being the strength of the static magnetic field of the system that the coil is compatible with and hence adjustments to the corresponding frequency specific components.

Conclusion: GE Healthcare considers the 3.0T 16 Channel Head Neck Spine (HNS) Coil to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

NOV 25 2009

GE Healthcare Coils (USA Instruments, Inc.)
% Mr. Daniel W. Lehtonen
Official Correspondent
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K093348
Trade/Device Name: 3.0T 16 Channel Head Neck Spine Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 26, 2009
Received: October 27, 2009

Dear Mr. Lehtonen:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K093348

Device Name: 3.0T 16 Channel Head Neck Spine Coil

Indications for Use:

The GE 3.0T 16 Channel Head Neck Spine Coil is a receive-only RF coil designed for use with the 3.0T MRI system manufactured by GE Healthcare. The coil is intended for imaging of the brain; cervical, thoracic and lumbar spines; as well as the soft tissues and vasculature of the head, neck, and upper chest. The nucleus excited is hydrogen.

Prescription Use_X___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K093348