JAN 12 2011

510(k) Summary

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

Date:	November 16, 2010
Submitter:	GE Healthcare Coils (USA Instruments, Inc.) Establishment Registration Number: 1529041 1515 Danner Dr. Aurora, OH 44202, USA
Primary Contact Person:	Mr. Michael S. Preto Regulatory Affairs Leader, MR GE Healthcare Coils (USA Instruments, Inc.) Phone: +1 330 995-8333 Fax: +1 330 562-1422 Email: michael.preto@ge.com
Secondary Contact Person:	Mr. Glen Sabin Regulatory Affairs Director, MR GE Healthcare (GE Medical Systems, LLC) Establishment Registration Number: 2183553 3200 N Grandview Blvd., Mail Code – W-827 Waukesha, WI 53188, USA Phone: +1 262 521 6848 Fax: +1 262 521 6439 Email: glen.sabin@ge.com
Device: Trade Name:	Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil
Common/Usual Name:	Coil, magnetic resonance, specialty
Classification Names:	21 CFR 892.1000, Magnetic resonance diagnostic device
Product Code:	90MOS
Predicate Device(s):	K030371, USA Instruments Prima III TotalSENSE Torso Coil

Device Description:	The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil are surface coils used for Magnetic Resonance Imaging. They are tuned to image Proton nuclei in a receive-only configuration. They are comprised of 32 individual Phased Array coil elements each utilizing an integrated preamplifier to improve image quality. The geometry is optimized for use with parallel imaging techniques. The 16 Ch version uses multiplexers to allow a 32 channel design to be used on 16 Channel systems.
Intended Use:	The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil are receive-only RF Coils designed for use with 3.0T MRI systems manufactured by GE Healthcare. The indications for use include chest, cardiac, abdomen, torso, pelvis, prostate, hips, and long bone imaging. The nucleus detected is hydrogen.
Technology:	The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil are 32-element phased array RF receive only coils with integrated preamplifiers. The coil designs consist of RF chokes with fast switching PIN 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 device. The 16 Ch version uses multiplexers to allow a 32 channel design to be used on 16 Channel systems
Determination of Substantial Equivalence:	The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil have comparable indications for use as their predicate device and the same or similar non-clinical voluntary standards are used to demonstrate substantial equivalence of safety and performance: IEC 60601-1: Electrical Safety – compliant with all applicable sections IEC 60601-1-2: Electromagnetic Compatibility – compliant with all applicable sections (i.e. electrostatic discharge) IEC 60601-2-33: Electrical Safety – compliant with all applicable sections (i.e. documentation requirements) ISO 10993-1: Biocompatibility – determination of post market acceptability of materials SNR testing according to the method identified in Section 18. The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil have increased channel and larger coverage area than the TotalSENSE Torso Coil. They share a similar high-level phased array, receive-only design.
Conclusion:	GE Healthcare considers the Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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. Michael S. Preto
Regulatory Affairs Leader-MR
GE Healthcare Coils (USA Instruments, Inc.)
1515 Danner Drive
AURORA OH 44202

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Re: K103365
Trade/Device Name: Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 16, 2010
Received: November 18, 2010

Dear Mr. Preto:

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

510(k) Number (if known): K103365

Device Name: Discovery 3T 16 Ch Body Array Coil and
Discovery 3T 32 Ch Body Array Coil

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Indications for Use:

The Discovery 3T 16 Ch Body Array Coil and Discovery 3T 32 Ch Body Array Coil are receive-only RF Coils designed for use with 3.0T MRI systems manufactured by GE Healthcare. The indications for use include chest, cardiac, abdomen, torso, pelvis, prostate, hips, and long bone imaging. The nucleus detected 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

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

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