4 510(k) Summary

510(k) Summary (As required by section 21 CFR 807.92(c))	
Submitter:	MR Instruments, Inc. 5610 Rowland Drive, Suite 145 Minnetonka, MN 55343
Contact Person:	Robert Beck Director, RA/QA Telephone: 952-200-0297 Email: rbeck@mrinstruments.com JUL 25 2013 MR Instruments, Inc. 5610 Rowland Drive, Suite 145 Minnetonka, MN 55343
Date Prepared:	December 13, 2012
Trade Name:	DuoFLEX® Coil Suite, Model FC1500G-8R
Common/Usual Name:	Specialty Magnetic Resonance Coil
Classification:	21 CFR 892.1000 Magnetic Resonance Diagnostic Device, Class II
Product Code:	MOS
Manufacturer:	MR Instruments, Inc. 5610 Rowland Road, Suite 145 Minnetonka, MN 55343
Establishment Registration:	3003852428
Predicate Device:	• GE 1.5T 6-Channel Phased Array Flex Coil (K110610)

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Device Description:	The MR Instruments FC1500G-8R DuoFLEX® Coil Suite includes three different sets of coil paddles and a single, shared preamplifier box (the "Connector Box") with a system connector. One set of coil paddles is a pair of 24cm square containing four loops/channels per paddle for a total of eight channels for the two paddles. The second set of paddles is a pair of 10cm square containing four loops/channels per paddle for a total of eight channels for the two paddles. The third set of paddles is a single rectangular, interventional coil containing a single planar loop. All of these paddles connect to the same connector box containing eight preamplifiers; only one pair can be connected at a time. The coil design for all of the paddles has the same, simple antennae design and the same system connectivity configuration. The coils can be used in several configurations, including any single coil and any two coils, providing 1, 5 or 8 channels for imaging.
Intended Use	The DuoFLEX Coil Suite is indicate for use on the order of the physician in conjunction with a 1.5T MRI scanner, as an accessory to product 2D and 3D images. The DuoFLEX Coil Suite is for use with GE Healthcare MR Systems .
Comparison of Technological Characteristics:	Similarities between the subject device and the predicate device are that they are all receive-only RF coils designed to be flexibly positioned on the human anatomy. All devices are designed for ease of positioning to deal with variations between patient anatomies. The primary difference is in the number of RF elements. The subject device as well as the predicate device uses the same basic technology to perform the same basic function, which is the use of Magnetic Resonance Imaging systems to provide images of various body parts. The *GE 1.5T 6-Channel Phased Array Flex Coil* (K110610) is designed to be used either as a pair of coils or as a single coil, and is designed to be flexible enough to accommodate itself to various anatomical positions. These same statements can be made for the DuoFLEX Coil Suite.

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Summary of Technical Comparisons	The comparison of the DuoFLEX Coil Suite to the predicate device with respect to intended use, target population, technological characteristics and principles of operation confirms substantial equivalence. The fundamental performance and functional characteristics of the DuoFLEX Coil Suite is very similar to the predicate GE 1.5T 6-Channel Phased Array Flex Coil (K110610). The DuoFLEX Coil Suite includes three sizes of coils that are more flexible than the GE 1.5 6-Channel Phased Array Flex Coil.

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Non-Clinical Testing:	The following bench testing was conducted on the DuoFLEX Coil Suite: • EMC and electrical safety testing. • Electrical and mechanical safety testing. • System safety testing. • Performance testing with phantoms. • Predicate device comparison tests. • Volunteer scans. • Per IEC 60601-1: o Humidity Preconditioning for Dielectric Test o Determination of Accessible Parts o Legibility of Markings o Durability of Markings o Dielectric Strength o Ball Pressure o Creepage Distances and Air Clearance o Surfaces, Corners and Edges o Instability in Transport Position o Instability Excluding Transport o Cleaning, disinfection of ME equipment o Mold Stress Relief o Impact Test o Push Test o Drop test portable ME equipment The following testing has been performed to support substantial equivalence (see Table 9): • Biocompatibility for patient contact materials. • NEMA MS-1 Signal to Noise Ratio. • Image Uniformity Comparison. • Clinical comparison for image quality. • Phantom (cadaver) simulated interventional use. The following quality assurance measures were applied during development of this device (appendices D, F, G): • Failure Mode Effects Analysis/Hazard Analysis (FMEA). • Design FMEAs for mechanical and RF designs. • Performance Requirements Testing including Final Bench Testing, ISO 60601 Testing, Surface Temperature Testing, SNR per NEMA MS-1 and MS-6, and Image Uniformity.
Design Validation	Design validation was performed using the DuoFLEX Coil Suite in actual and simulated use settings. The results support substantial equivalence to both predicate devices and demonstrate that the DuoFLEX Coil Suite is safe for its intended use.

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Clinical Testing:	This technology is not new, therefore a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.
Conclusion:	We conclude that the results of testing show the DuoFLEX Coil Suite to be substantially equivalent to the predicate devices. The DuoFLEX Coil Suite has the same technological characteristics as the predicate device in that all devices are receive-only RF coils intended for use with MRI equipment. The DuoFLEX Coil Suite has the same intended uses as the predicate devices in that all devices are intended for diagnostic imaging. It has been shown in this 510(k) submission that the differences between the DuoFLEX Coil Suite and the GE 1.5T 6-Channel Phased Array Flex Coil (K110610). do not raise any questions regarding safety and effectiveness. The DuoFLEX Coil Suite, as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

MR Instruments, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130706
Trade/Device Name: DuoFLEX Coil Suite (1.5T)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 10, 2013
Received: July 11, 2013

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 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. 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
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): K130706

Device Name: **MR Instruments, Inc.**
DuoFLEX® Coil Suite FC1500G-8R

Indications for Use:

The DuoFLEX Coil Suite is indicate for use on the order of the physician in conjunction with a 1.5T MRI scanner, as an accessory to product 2D and 3D images. The DuoFLEX Coil Suite is for use with GE Healthcare MR Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130706