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

November 28, 2017

Re: K173290
Trade/Device Name: DuoFLEX® Coil Suite
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 13, 2017
Received: November 14, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173290

Device Name
DuoFLEX® Coil Suite

Indications for Use *(Describe)*
The 1.5T GE and Siemens DuoFLEX® Coil Suites and the 3.0T GE and Siemens DuoFLEX® Coil Suites are indicated for use on the order of a physician in conjunction with a 1.5T GE Healthcare and Siemens Healthcare Magnetic Resonance Scanner system and a 3.0T GE Healthcare and Siemens Healthcare Magnetic Resonance Scanner system to produce 2D and 3D images that when interpreted by a trained physician yield information that may assist in diagnosis.

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 (As required by section 21 CFR 807.92(c))	
Submitter:	MR Instruments, Inc. 5610 Rowland Drive, Suite 145 Minnetonka, MN 55343
Contact Person:	Leon Ricord Director, Regulatory & QA Telephone: 952-229-8812 Email: lricord@mrinstruments.com MR Instruments, Inc. 5610 Rowland Drive, Suite 145 Minnetonka, MN 55343
Date Prepared:	November 8th, 2017
Trade Name:	DuoFLEX® Coil Suite
Common / Usual Name:	Specialty Magnetic Resonance Coil
Classification:	21 CFR 892.1000
Product Code:	MOS
Manufacturer:	MR Instruments, Inc. 5610 Rowland Road, Suite 145 Minnetonka, MN 55343
Establishment Registration:	3003852428
Predicate Device(s):	DuoFLEX Coil Suite (1.5T), **K130706**
Device Description:	The MR Instruments FC 1520G-8R, FC 3000G-8R, FC 1500S-8R, and FC 3000S-8R Coil Suites are identical with the only exceptions: • FC 1520G-8R (GE MR Systems @ 63.86MHz with GE System Connector Plug) • FC 3000G-8R (GE MR Systems @ 127.73MHz with GE System Connector Plug) • FC 1500S-8R (Siemens MR Systems @ 63.6MHz with Siemens System Connector Plug) • FC 3000S-8R (Siemens MR Systems @ 123.23MHz with Siemens System Connector Plug) The coil suites include two different sets of coil paddles and a single, shared preamplifier box (the "Connector Box") with a system connector. One set contains a pair of coil paddles containing four 24cm loops/channels per paddle for a total of eight channels for the two paddles. The second set contains a pair of coil paddles containing four 10cm loops/channels per paddle for a total of eight channels for the two paddles. 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 the paddles has the same, simple antennae design and the same system connectivity configuration. The coils can be used in the following configurations: • 24cm by itself

	• 24cm with 24cm • 24cm with 10cm • 10cm with 10cm The aforementioned configurations provide 4 or 8 channels for imaging.
Intended Use:	The 1.5T GE and Siemens DuoFLEX® Coil Suites and the 3.0T GE and Siemens DuoFLEX® Coil Suites are indicated for use on the order of a physician in conjunction with a 1.5T GE Healthcare and Siemens Healthcare Magnetic Resonance Scanner system and a 3.0T GE Healthcare and Siemens Healthcare Magnetic Resonance Scanner system to produce 2D and 3D images that when interpreted by a trained physician yield information that may assist in diagnosis.

Comparison of Technological Characteristics:	The subject devices and the predicate device are identical except for the following differences:
	• Increased coil cable length by 12”
	• Replaced system cable with foam segments
	• Decreased system cable length by 6”
	• Added cylindrical balun to the system cable
	• Added an additional cylindrical balun to the coil cable
	• Improved & updated internal electronics
	• Three (3) of the Coil Suites’ field strength and frequency:
	  ○ Predicate Device = 1.5T @ 63.86MHz
	  ○ Subject Devices That Differ:
	  ▪ 1.5T @ 63.6MHz
	  ▪ 3.0T @ 127.73MHz
	  ▪ 3.0T @ 123.23MHz
	• Two (2) of the Coil Suites’ System Connector Plugs:
	  ○ Predicate Device = GE System Connector Plug
	  ○ Subject Devices = Siemens System Connector Plug
	
	The subject devices and the predicate device use the same technology to perform the same function which is the use of Magnetic Resonance Imaging systems to provide images of various body parts. The MR Instruments’ 1.5T DuoFLEX® Coil Suite (K130706) 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 new variations of the DuoFLEX® Coil Suites.

Summary of Technical Comparisons:	The comparison of the DuoFLEX® Coil Suites 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 Suites are identical to the predicate 1.5T DuoFLEX® Coil Suite (K130706).
Non-Clinical Testing:	The following bench testing was conducted on the DuoFLEX® Coil Suites: • 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:
	  ○ Humidity Preconditioning for Dielectric Test
	  ○ Determination of Accessible Parts
	  ○ Legibility of Markings
	  ○ Durability of Markings
	  ○ Dielectric Strength
	  ○ Ball Pressure
	  ○ Creepage Distances and Air Clearance
	  ○ Surfaces, Corners and Edges
	  ○ Instability in Transport Position
	  ○ Cleaning, disinfection of ME equipment
	  ○ Mold Stress Relief
	  ○ Impact Test
	  ○ Push Test
	  ○ Drop test portable ME equipment
	
	The following testing has been performed to support substantial equivalence:
	
	• Biocompatibility for patient contact materials
	• NEMA MS-1 Signal to Nosie Ratio
	• Image Uniformity Comparison
	• Evaluation of Sample Clinical Images (Clinical Evaluation Testing)
	
	The following quality assurance measures were applied during development of this devices (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 Suites in actual and simulated use settings. The results support substantial equivalence to the predicate device and demonstrate that the DuoFLEX® Coil Suites are safe for its intended use.
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 devices as the indications for use is equivalent to the predicate device. The substantial equivalence of the devices is supported by the non-clinical testing.

Conclusion:	We conclude that the results of testing show the DuoFLEX® Coil Suites to be substantially equivalent to the predicate device. The DuoFLEX® Coil Suites have the same technological and functional characteristics as the predicate device in that all devices are receive-only RF coils intended for use with MRI equipment. The DuoFLEX® Coil Suites have the same intended use as the predicate device in that all devices are intended for diagnostic imaging. It has been shown in this 510(k) submission that the difference between the DuoFLEX® Coil Suites and the 1.5T DuoFLEX® Coil Suite (K130706) do not raise any questions regarding safety and effectiveness. The DuoFLEX® Coil Suites, as designed and manufactured, are substantially equivalent to, and as safe and effective as, the referenced predicate device.