MAY 2 0 2013

Section 8. 510(k) Summary

Submitter's Name, Address, telephone number, a contact person and date the summary was prepared:

Submitter's Name:	Resonance Innovations LLC
Submitter's Address:	9840 South 140th St., Suite 8 Omaha, NE 68138
Submitter's Telephone:	402-934-2650
Submitter's Contact:	Randall Jones, President
Date 510(k) summary prepared:	February 15, 2013

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name:	Extremity Coil Family
Common or Usual Name:	MRI coil(s)
Classification Name:	Coil, Magnetic Resonance, Specialty
Classification Code:	MOS
Predicate Device:	1.5T ScanMed PV Array

Description of the Device

The individual coils that comprise the Extremity Coil Family interface with a 3.0 Tesla, 8-channel MRI scanner.

Device Model Number	Device Description
148GE3000	Distal Extremity Coil
169GE3000	Long Bone Coil – large
308GE3000	Elbow Coil

Table 1 Device Descriptions

All coils included in the Extremity Set are extremely similar in design, construction, materials and operation. There are slight variations in physical size (to accommodate differing patient sizes), and slight physical housing variations (required to optimize the image quality depending on the extremity anatomy). The designs and materials used to manufacture the individual coils are nearly identical and are no different from standard MRI coil technology that has existed for years. The geometry of each coil housing has been formed by utilizing a semi-rigid housing in conjunction with semi-flexible flaps and/or

padding that facilitates close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest on a broad size variation of patient anatomy. All employ similar blocking, impedance matching and integrated pre-amplifier circuitry. For these reasons, it is warranted to bundle these devices into one 510(k) submission.

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

May 20, 2013

Resonance Innovations, LLC
% Randall Jones, Director of Engineering
President & CEO
9840 S. 140th Street, Suite 8
OMAHA NE 68138

Re: K130457
Trade/Device Name: Extremity Coil Family
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: May 14, 2013
Received: May 15, 2013

Dear Mr. Jones:

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,

Michael D. O'Hara for

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): K130457

Device Name: Extremity Coil Family

Indications for Use:

The intended use for the device family is to provide form fitting MRI antenna sets to facilitate targeting imaging of various musculoskeletal extremity regions using a GE 3.0T MRI scanner. The Indications for use are:

- Soft tissue and bone imaging of the extremities as allowed by the MRI system.
- Magnetic resonance peripheral angiography.

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)

Michael D. O'Hara

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

510(k)__K130457