Section 8. 510(k) Summary

k133986

JAN 27 2014

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: January 22, 2014

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: Orbit and Mandible Array Family

Common or Usual Name: MRI coil(s)

Classification Name: Coil, Magnetic Resonance, Specialty

Classification Code: MOS

Predicate Device: Pediatric Array Coil (K951649)

Description of the Device

The devices are a 1.5T Orbit and Mandible Array and a 3.0T Orbit and Mandible Array. The designs and materials used to manufacture each coil are no different from standard MRI coil technology that has existed for years. The geometry of each coil housing is formed by an EVA foam cover around a flexible circuit board. The two devices in this family are identical except for the tuned frequency. For this reason, it is warranted to bundle these two devices into one 510(k) submission.

The following devices are bundled in this submission.

Device Name	Model Number	Operational Field Strength of MRI System
1.5T Orbit and Mandible Array	994GE1500	1.5T
3.0T Orbit and Mandible Array	992GE3000	3.0T

Indications for Use

The family is to be used in conjunction with a GE 1.5T and GE 3.0T Magnetic Resonance Scanner, to produce diagnostic images of the orbits and surrounding anatomy, as well as mandible regions that can be interpreted by a trained physician.

The intended use for the device family is to provide MRI antenna sets to facilitate targeting imaging of the orbit region and mandible region.

- Tissue of the brain and face with emphasis on the orbits, and of the mandible joint of the head.

Technological Characteristics

The differences between the predicate and the current submission are described, below.

1.) Design. The submission is for a smaller subset of anatomies of the larger predicate, itself having elements close to the patient's orbits. Very much similarly, this new submission of the Orbit & Mandible Family utilizes smaller dedicated loops closer to the patient's face.

2.) Material. The distinction between the predicate and Orbit & Mandible Family group is non-substantive in that they both have insulating qualities proven by dielectric withstand testing, and have passed liquid ingress testing.

3.) Chemical Composition. Both products, the predicate and the recent submission, have biocompatible construction as demonstrated by cytotoxicity testing and by their history of use in previously cleared devices.

4.) Energy Source. Both of these products are receive-only coils not generating their own power, but rather stimulated by the MRI system as an energy source.

Non-clinical tests

The coils have similar dimension in the head area and have induced similar fields by the transmit coils that stimulate them. The predicate and current submission were compared by similar risk management efforts, as listed below, and determined to be substantially equivalent.

- Sensitivity Profile
- SNR Analysis
- Hazard Analysis
- FMEA
- Blocking Analysis
- Heat Tests

Clinical tests

Analyses in all 3-planes (sagittal, coronal and transverse) were run to show that the anatomies of the submitted and predicate coils have substantial equivalence; the predicate device images the complete brain including orbits, and the Orbit & Mandible Family submission simply dedicates to a more local, higher-resolution performance on the orbits and mandible.

Final Discussion

As described in the Design section, above, the submission is for smaller loops dedicated more closely to the patient's face, with the coils offering no energy source, and exhibiting strong decoupling; thus, the study determines that the submitted device is as safe, as effective, and performs as well or better than the legally-marketed device on the target anatomies.

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

January 27,2014

RESONANCE INNOVATIONS LLC
RANDALL JONES
PRESIDENT
9840 SOUTH 140TH ST., SUITE 8
OMAHA NE 68138

Re: K133986
Trade/Device Name: Orbit and Mandible Array Family
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: December 31, 2013
Received: January 06, 2014

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.

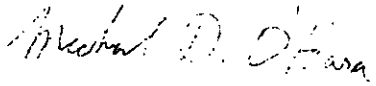
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



For

Janine 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): **k133986**

Device Name: Orbit and Mandible Array Family

Indications for Use:

The Indications for use are as follows:

- The family is to be used in conjunction with a GE 1.5T and GE 3.0T Magnetic Resonance Scanner, to produce diagnostic images of the orbits and surrounding anatomy, as well as mandible regions that can be interpreted by a trained physician.
- The intended use for the device family is to provide MRI antenna sets to facilitate targeting imaging of the orbit region and mandible region.
  - Tissue of the brain and face with emphasis on the orbits, and of the mandible joint of the head.

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