Shanghai United Imaging Healthcare Co., Ltd.
Xin Gao
Regulatory Affairs Specialist
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, 201807 Cn

February 8, 2019

Re: K183186
Trade/Device Name: Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 15, 2018
Received: November 19, 2018

Dear Xin Gao:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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 A. 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)*
K183186

Device Name
Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24

Indications for Use *(Describe)*
Head Coil - 12 is a 12 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for head imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Head Coil - 32 is a 32 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for head imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Carotid Coil - 8 is an 8 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for obtaining diagnostic images of carotid. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Temporomandibular Joint Coil - 4 is a 4 channel receive-only RF Coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for diagnostic images of the mandible region. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Infant Coil - 24 is a 24 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for imaging of the infant's brain, spine, heart, torso and extremities. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Cardiac Coil - 24 is a 24 channel receive-only RF Coil designed for use with UIH 3.0T MRI systems. The indications for use include imaging of the heart, and mediastinum regions. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
Foot & Ankle Coil - 24 is a 24 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for foot and ankle imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the 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

1. Date Prepared [21 CFR 807.92(a)(1)]

November 15, 2018

2. General Information [21 CFR 807.92(a)(1)]

Manufacturer: Shanghai United Imaging Healthcare Co., Ltd
2258 Chengbei Rd., Jiading District, Shanghai, 201807

Contact Person: Xin GAO
Regulatory Affairs Specialist
Tel: +86 (21) 67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name:	Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24
Common Name:	Magnetic Resonance Diagnostic Device
Model:	Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24
Product Code:	MOS
Regulation Number:	21 CFR 892.1000
Device Class:	II

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification of predicate devices within this submission are as follow:

Predicate Device 1

Manufacturer:	GE Healthcare Coils (USA Instruments, Inc.)
Device Name:	48CH Head Coil
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K163205

Predicate Device 2

Manufacturer:	Quality Electrodynamics, LLC
Device Name:	16ch Foot/ Ankle SPEEDER
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K181697

Predicate Device 3

Manufacturer:	INVIVO
Device Name:	CARDIOVASCULAR ARRAY COILS
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K061952

Predicate Device 4

Manufacturer:	Resonance Innovations LLC
Device Name:	Orbit and Mandible Array Family
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K133986

Predicate Device 5

Manufacturer:	Shanghai Chenguang Medical Technologies Co., Ltd
Device Name:	Carotid Coil
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K112002

Predicate Device 6

Manufacturer:	Quality Electrodynamics, LLC
Device Name:	Pediatric 16, A 3T Tim Coil
Product Code:	MOS
Device Class:	II
Regulation Number:	21 CFR 892.1000
FDA 510 (k) #:	K140998

5. Device Description [21 CFR 807.92(a)(4)]

Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24 are receive-only multi-channel phased array coils designed for use with UIH 3T MRI systems. The suffix number in coil name stands for the receive channel of the coil. The resonant nucleus is hydrogen protons (1H). All coil elements are protected from transmit field by both active and passive decoupling circuits. Each coil is designed to provide optimum image quality for its dedicated human anatomy region as defined in intended use.

6. Intended Use [21 CFR 807.92(a)(5)]

- Head Coil - 12 is a 12 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for head imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
- Head Coil - 32 is a 32 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for head imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
- Carotid Coil - 8 is an 8 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for obtaining diagnostic images of carotid. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
- Temporomandibular Joint Coil - 4 is a 4 channel receive-only RF Coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for diagnostic images of the mandible region. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
- Infant Coil - 24 is a 24 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for imaging of the infant's brain, spine, heart, torso and extremities. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.
- Cardiac Coil - 24 is a 24 channel receive-only RF Coil designed for use with UIH 3.0T MRI systems. The indications for use include imaging of the heart, and mediastinum regions. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.

- Foot & Ankle Coil - 24 is a 24 channel receive-only RF coil designed for use with UIH 3.0T MRI systems. The coil is indicated for use for foot and ankle imaging. When interpreted by a trained physician, these images provide information that can be useful in the determination of the diagnosis.

7. Technological Characteristic [21 CFR 807.92(a)(6)]

Head Coil - 12, Head Coil - 32, Carotid Coil - 8, Temporomandibular Joint Coil - 4, Infant Coil - 24, Cardiac Coil - 24, Foot & Ankle Coil - 24 are built with well-established technology and design principles in the industry.
All coils are formed with linear loop coils resonant at the MR system frequency into a phased array. Each coil element is connected to an independent low noise amplifier with a low noise figure to maintain optimum SNR.
Two means of protection from RF transmit field are used for each coil element. An active decoupling circuit is controlled by a PIN diode driven by external control signal provided by the MR system. A passive decoupling circuit is also used in case the coil is left unplugged in the system bore.
The rigid coil enclosures are designed with shape matching the anatomy. Flexible flaps are also used in some coils to enhance patient comfort and adjustability. Coil materials are test to be flame and impact resistant, and biocompatible.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Summary of Non-Clinical Tests:
The following testing was conducted on the proposed devices as the predicate devices:

- ES60601-1:2005/(R)2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-2-33 Ed. 3.1:2013, Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnostic
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- MS 1-2008(R2014), Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 3-2008(R2014), Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 6-2008(R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging
- MS 9-2008(R2014), Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images

The test results demonstrated that the devices performs as expected and thus, it is substantially equivalent to the predicate devices to which it has been compared.

Summary of Clinical Tests:

- Sample clinical images were provided to support the ability of the proposed devices to generate diagnostic quality images in accordance with the MR guidance on premarket notification submissions.

9. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we conclude that the proposed devices substantially equivalent to the predicate devices. They do not introduce new indications for use, and have the same technological characteristics and do not introduce new potential hazards or safety risks.