DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Shenzhen RF Tech Co., Ltd.
% Mr. Mike Gu
Regulatory Affairs Manager
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Baiyun District, Guangzhou, Guangdong 510420
CHINA

June 28, 2016

Re: K151653
Trade/Device Name: 8ch Foot Ankle Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 8, 2015
Received: July 10, 2015

Dear Mike Gu:

This letter corrects our substantially equivalent letter of August 7, 2015.

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151653

Device Name
8ch Foot Ankle Coil

Indications for Use *(Describe)*

8ch Foot Ankle Coil manufactured by RFT is a receive-only RF surface coil designed for use with the SIGNA Pioneer only. 8ch Foot Ankle Coil is indicated to use for foot and ankle imaging. The nucleus excited is hydrogen.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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CEO

Shenzhen RF Tech Co.,Ltd

Date Prepared: May 08, 2015

II. DEVICE

Name of Device: 8ch Foot Ankle Coil

Common/Usual Name: Coil, Magnetic Resonance, Specialty

Classification Names: Magnetic resonance diagnostic device (21 CFR 892.1000)

Regulation Class: II

Product Code: MOS

Model: RFT Model Number: 10-F21457

GE Part Number: 5567773-2

This device is manufactured by RFT and distributed by GE Medical Systems, LLC.

III. PREDICATE DEVICE

Primary predicate device: MRI'S FAC-127 Foot and Ankle Coils, K050514;

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The 8ch Foot Ankle Coil is a surface coil used for Magnetic Resonance Imaging. It's tuned to image Proton nuclei in a receive-only configuration. It is comprised of 8 individual Phased Array coil elements which receive the signal from patient's foot or ankle. Preamplifiers are integrated in the coil. The geometry is optimized for use with parallel imaging techniques.

The 8ch Foot Ankle Coil receives foot or ankle signal through 8-element phased array under 3T static magnetic field and presents the foot or ankle images based on the above mentioned theory.

The 8ch Foot Ankle Coil comprises the coil and the base plate. The coil conforms to patients' anatomy, accommodating various foot contours while minimizing patient discomfort. The base plate separated from the coil part is used to place the patients' anatomy on the table.

The associated accessories include:

- 1 cable
- 1 baseplate,
- 1 ankle pad,
- 1 foot pad,
- 1 ramp pad,
- 1 knee pad support,
- 1 strap.

V. INDICATIONS FOR USE

8ch Foot Ankle Coil manufactured by RFT is a receive-only RF surface coil designed for use with the SIGNA Pioneer only. 8ch Foot Ankle Coil is indicated to use for foot and ankle imaging. The nucleus excited is hydrogen.

The Indications for Use statement for the 8ch Foot Ankle Coil is not identical to the predicate device; however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both Indications for Use statements indicate that the device is intended to be used in conjunction with a 3T MR system to produce images of the knee and foot, and that the images can be interpreted by a trained physician.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The 8ch Foot Ankle Coil employs the same technology as its predicate device K050514.

At a high level, the subject and predicate are based on the following same technological elements:

- Receive phased array RF coils;
- Compatible with 3T MR systems ;
- Active PIN diode switching blocking circuitry. Passive blocking circuitry;
- 8 channels;
- Lexan 940 polycarbonate housing material.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing:

The biocompatibility evaluation for the 8ch Foot Ankle Coil was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Under the conditions of the study, the result of biocompatibility testing demonstrated that the 8ch Foot Ankle Coil is not a sensitizer or an irritant, and is non-cytotoxic.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the 8ch Foot Ankle Coil. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Bench testing:

The following Bench tests were conducted, submitted, referenced or relied on to demonstrate the 8ch Foot Ankle Coil are safe and effective, the proposed device's performance meets the requirements of pre-defined acceptance criteria and intended use:

- Blocking Network analysis - This test determines the effectiveness of the blocking networks(s) for transmit decoupling to ensure safety and to minimize BI distortion.
- Surface temperature test - normal condition.
- Surface temperature test - unplugged condition.
- elements signal check;
- max B1;

Clinical tests

Analyses in sagittal, coronal, and axial planes were run on the 8ch Foot Ankle Coil to show that anatomies of the submitted and predicate coils have substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data and the clinical data support the safety of the device. The device should perform as intended in the specified use conditions. Shenzhen RF Tech Co., Ltd. considers the 8ch Foot Ankle Coil does not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.