DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2016

Shenzhen RF Tech Co., Ltd.
% Mr. Ke Xi
CEO
2-f, Bld4, Juhui Industrial Park, Tianliao, Guangming
Shenzhen, Guangdong 518132
CHINA

Re: K160935
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: June 30, 2016
Received: July 1, 2016

Dear Mr. Xi:

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,

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

510(k) Number *(if known)*

K160935

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 GE 1.5T MRI systems. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

I. Submitter

Shenzhen RF Tech Co., Ltd

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Phone: (+86) 755-2664 1989

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Contact Person: Mr. Ke Xi

CEO

Shenzhen RF Tech Co., Ltd

Email: xike@rft.cn

Date Prepared: March 31, 2016

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-F23936

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

III. Predicate Device

Predicate device: K122694, GE 8CH Foot Ankle Coil;

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 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.

V. Intended Use

8ch Foot Ankle Coil manufactured by RFT is a receive-only RF surface coil designed for use with GE 1.5T MRI systems. 8ch Foot Ankle Coil is indicated to use for foot and ankle imaging. The nucleus excited is hydrogen.

VI. COMPATIBILITY

The connector of 8ch Foot Ankle Coil is p-port. The 1.5T 8ch Foot Ankle Coil is compatible with GE 1.5T MRI systems where coil ID allows.

For example:

GE SIGNA Voyager 1.5T system

GE Optima MR450W 1.5T system

GE Discovery MR450 1.5T system

VII. Technology

8ch Foot Ankle Coil is 8-channel phased array RF receive only coils with integrated preamplifiers. The coil designs consist of RF chokes with switching diodes to provide decoupling which isolates the coil elements from RF fields during RF transmission. This coil is designed based on the same technology as the predicate device.

VIII. Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

Verification testing has been performed and is documented in the sections noted below of this submission. The following verification tests have been performed:

1. Biocompatibility testing (Section 15)
2. IEC 60601-1-2 testing (Section 17)
3. IEC 60601-1 testing (Section 17)
4. Maximum B1 Peak test (section 18)

5. Signal to Noise ratio and uniformity test according to NEMA standard (section 18)
6. Blocking Network analysis (section 18)
7. Surface temperature test - normal condition (section 18)
8. Surface temperature test - unplugged condition (section 18)

Summary of Clinical Tests:

Sample clinical images included in Section 20 were performed with all compatible GE 1.5T MRI systems. All sample clinical images are provided in all three imaging planes.

IX. Conclusion

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.