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

SHENZHEN RF TECH CO., LTD.
C/O ELENA LU
CONSULTANT
ROOM 1122, INTERNATIONAL MAYORS COMMUNICATION CENTRE
SHENZHEN, 518000
CHINA

August 1, 2016

Re: K160932
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: May 25, 2016
Received: July 5, 2016

Dear Ms. Lu:

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, PhD
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 below.

510(k) Number *(if known)*
K160932

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 3.0T 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	Mar., 25, 2015
Manufacturer information	Company title: Shenzhen RF Tech Co., Ltd. Company address: 2-F, Bld4, Juhui Industrial Park, Tianliao, Guangming, Shenzhen, P.R.China 518132 Phone: +86-755-2664 1989 Fax: +86-755-2664 2989 Contact Person: Mr. Ke Xi E-mail: xike@rft.cn
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Ms. Elena. Lu; Mr. Field. Fu E-Mail: elena@cefda.com; cefda13485@163.com
Establishment registration number	

5.2 Device Information

Type of 510(k) submission:	Special
Trade Name:	8ch Foot Ankle Coil
Model:	10-F21457
Classification name:	Magnetic resonance diagnostic device
Review Panel:	Radiology

Product Code:	MOS
Device Class:	II
Regulation Number:	892.1000

5.3 Predicate Device Information

Sponsor:	Shenzhen RF Tech Co., Ltd.
Device:	8ch Foot Ankle Coil
510(K) Number:	K151653

5.4 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.

5.5 Intended Use/Indications for Use

8ch Foot Ankle Coil manufactured by RFT is a receive-only RF surface coil designed for use with GE 3.0T MRI systems. 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 GE 3.0T MRI system to produce images of the knee and foot, and that the images can be interpreted by a trained physician.

5.6 Compatibility

The connector of 8ch Foot Ankle Coil is p-port. The 3.0T 8ch Foot Ankle Coil is compatible with GE 3.0T MRI systems where coil ID allows.
Such as:
GE Discovery 750W 3.0T system
GE Discovery MR750 3.0T system
GE SIGNA PET/MR 3.0T system

For GE SIGNA PET/MR system, 8ch Foot Ankle Coil is only compatible with the MR scanner of PET/MR, is not optimized for PET scanner, and may compromise PET image quality.

5.7 Technological characteristics of the proposed device compared to the predicate device

The proposed device and the predicate device have similar intended use, same technological characteristics, and similar material composition. The only difference in the design is the baseplate, which is modified to make the coil easy to be compatible with different GE 3.0T MRI systems. However, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the proposed device is substantially equivalent to the predicate devices.

5.8 Brief discussion of the nonclinical tests

The following performance data: SNR test report, Surface temperature test report and Uniformity test report for each GE 3.0T MRI system were provided in support of the substantial equivalence determination.

5.9 Brief discussion of clinical tests

Not applicable.

5.10 Other information (such as required by FDA guidance)

No other information.

5.11 Conclusions

The non-clinical data support the safety and effectiveness 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.