December 8, 2017

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

Re: K172222
Trade/Device Name: 8ch Flex Suite
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 20, 2017
Received: November 29, 2017

Dear Mr. Ke 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.

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.

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 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 below.

510(k) Number *(if known)*
K172222

Device Name
8ch Flex Suite

Indications for Use *(Describe)*
The 1.5T 8ch Flex Suite manufactured by Shenzhen RF Tech Co.,Ltd is receive-only coil and is designed for use as general purpose coil. The 1.5T 8ch Flex Suite is designed to be use with GE 1.5T MRI systems to produce diagnostic images of upper and lower extremities, head and spine that can be interpreted by a trained physician.

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.

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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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Shenzhen, 518132 China
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: July 20, 2017

II. Name of Device

Name of Device:	8ch Flex Suite
Common/Usual Name:	Coil, Magnetic Resonance, Specialty
Classification Names:	Magnetic resonance diagnostic device (21 CFR 892.1000)
Regulation Class:	II
Product Code:	MOS

III. Model numbers

10-F26000	8ch Flex Suite
10-F24260	8ch Flex 70 Array
10-F24261	8ch Flex 50 Array
10-F24262	8ch Flex 40 Array

IV. Predicate Device

Predicate device: K101632, 1.5T MetaFlexCoil;

V. Device Description

The 1.5T 8ch Flex Suite is receive-only phased array coil for imaging the upper and lower extremities, head and spine in adult population. The 1.5T 8ch Flex Suite consists of three flexible and lightweight coil of different size that can be wrapped or orientated flat, in order to accommodate various anatomic shapes and sizes.

The 1.5T 8ch Flex Suite is tuned to receive RF frequency corresponding to the proton precession in a 1.5 Tesla magnetic field, which is governed by the Larmor equation.

VI. Intended Use

The 1.5T 8ch Flex Suite manufactured by Shenzhen RF Tech Co.,Ltd is receive-only coil and is designed for use as general purpose coil. The 1.5T 8ch Flex Suite is designed to be use with GE 1.5T MRI systems to produce diagnostic images of upper and lower extremities, head and spine that can be interpreted by a trained physician.

VII. Compatibility

The 1.5T 8ch Flex Suite is compatible with GE 1.5T MRI systems (Such as: SIGNA Explorer system) where coil ID allows. The 1.5T 8ch Flex Suite is intended for use on 1.5T GE Magnetic Resonance Scanners with HD-Connectors (used on HD series scanners).

VIII. Technology

The 1.5T 8ch Flex Suite is flexible and can be wrapped around the anatomy of interest, which is similar to its predicate device.

The 1.5T 8ch Flex Suite is general purpose receive only coil with 8 elements and intergraded preamplifiers.

The 1.5T 8ch Flex Suite is based on phased array technique for combining the images from 8 different channels. The 1.5T 8ch Flex Suite is tuned to the proton frequency of 63.86MHz.

IX. 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
2. IEC 60601-1-2 testing
3. IEC 60601-1 testing
4. Maximum B1 Peak test
5. Signal to Noise ratio and uniformity test according to NEMA standard
6. Blocking Network analysis
7. Surface temperature test - normal condition
8. Surface temperature test - unplugged condition

Summary of Clinical Tests:

Analyses in axial, sagittal and coronal planes were run on the 8ch Flex Suite to show that anatomies of the submitted and predicate device have substantial equivalence.

X. Conclusion

Shenzhen RF Tech Co., Ltd considers the 8ch Flex Suite does not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.