Shenzhen RF Tech Co., Ltd.
℅ Mr. Gary Wang
Q&R Director
2-F, Bld4, Juhui Industrial Park, Tianliao, Guangming
Shenzhen, Guangdong 518132
CHINA

July 22, 2020

Re: K200836
Trade/Device Name: 8ch Flex Suite
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: June 18, 2020
Received: June 22, 2020

Dear Mr. Wang:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200836

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, spine and cardiac 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.

510(k) Summary

K200836

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

I. Applicant/Manufacturer

Shenzhen RF Tech Co., Ltd.
2-F,BLD4 Juhui Industrial Park,
Tianliao,Guangming,Shenzhen,
P.R.China 518132
Phone: (+86) 755-2664 1989-113
Fax: (+86)755-2664 2989

Submitter/Correspondent

Shenzhen RF Tech Co., Ltd.
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Phone: (+86) 755-2664 1989-113
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Contact Person:

Mr. Gary Wang
Q&R Director
Shenzhen RF Tech Co., Ltd.
Email: gary.wang@rft.cn

II. Name of Device

Common Name of Device:	8ch Flex Suite
Common/Usual Name:	Coil, Magnetic Resonance, Specialty
Classification panel:	Radiology
Classification Names:	Magnetic Resonance Diagnostic Device
Regulation Number:	21 CFR 892.1000
Regulation Class:	II
Product Code:	MOS
Type of 510(k) submission:	Traditional 510(k)

III. Device Information

Product Number:	Device Trade Name
10-F25061	8ch Flex 70 Array
10-F25062	8ch Flex 50 Array
10-F25063	8ch Flex 40 Array

IV. Predicate Device Information

Sponsor:	Shenzhen RF Tech Co., Ltd.
Device:	8ch Flex Suite
510(K) Number:	K172222

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.

10-F25061

10-F25062

10-F25063

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, spine and cardiac that can be interpreted by a trained physician.

VII. Comparison of Technological Characteristics with the Predicated Device

Specification	Predicate Device	Proposed	Discussio Differenc
K number	K172222		
Device name	8ch Flex Suite	8ch Flex Suite	
Manufacturer	Shenzhen RF Tech Co.,Ltd	Shenzhen RF Tech Co.,Ltd	
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.	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, spine and cardiac that can be interpreted by a trained physician.	Similar
Anatomical site	The upper and lower extremities, head and spine in adult populations that can be interpreted by a trained physician.	The upper and lower extremities, head, spine and cardiac in adult populations that can be interpreted by a trained physician.	Similar
Coil type	RF coil (receive only)	RF coil (receive only)	Same
Channel	8 CH	8 CH	Same

Field strength	1.5 T	1.5 T	Same
RF power	16kw	16kw	Same
amplitude	B1 max =25UT	B1 max =25UT	Same
rise time	330usec	330usec	Same
slew rate	100 T/m/s	100 T/m/s	Same
shielding	80dB	80dB	Same
cooling	12kw(water cooling)	12kw(water cooling)	Same
preamplifier noise	0.5dB	0.5dB	Same
Storage temperature	-30°C to +55°C	-30°C to +55°C	Same
Storage humidity	5% to 95%	5% to 95%	Same
Operation temperature	15° C to 21°C	15° C to 21°C	Same
Operating humidity	30% to 75%	30% to 75%	Same

Power source	+10V	+10V	Same
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-5 and ISO 10993-10	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
Other: Device Specific Guidance Requirements for Comparison	Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	Same

The proposed 8ch Flex Suite can be wrapped around the anatomy of interest and have same design and same technology character with same manufacturing process and material with predicate device.
The proposed 8ch Flex Suite is general purpose receive only coil with 8 elements and intergraded preamplifiers. It is same with predicate device
The proposed 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. It is same with predicate device
The proposed 8ch Flex Suite has similar intended purpose with predicate device.
The difference between proposed 8ch Flex Suite and predicate device is the plug type. The proposed 8ch Flex Suite is P port and predicate device is A port, which is connected to MRI system with different port. The proposed 8ch Flex Suite extended its image scope by adding cardiac image compared to predicate device.

VIII Standard List for Performance Tests

All verification tests have been performed according to below standard, the testing results are passed
1.IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +
A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential
2.IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;
3.ISO 10993-5:2009: Biological evaluation of medical devices. Part 5-Tests for in vitro cytotoxicity.
4.ISO 10993-10:2010 Biological evaluation of medical devices, Part 10-Tests for irritation and skin

sensitization.

5.NEMA MS-1-2008 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging.

6.NEMA MS 3-2008 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images.

7.IEC60601-2-33:2010+A1:2013+A2:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.

IX. Performance Data

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

The biocompatibility evaluation was conducted in accordance with ISO International Standard and included cytotoxicity test, sensitization test and irritation test to raw material which will contact with surface skin.

The test for safety and electromagnetic compatibility (EMC), basic safety and performance test were conducted in accordance with IEC and NEMA Standard.

Shelf Life testing and mechanical reliability testing were conducted.

Clinical images evaluation testing for the proposed device was evaluated by connected to compatible MRI system.

Summary: Based on above testing, the proposed 8ch Flex Suite was found to have a safety and effectiveness profile that is similar to the predicate device.

X. Conclusion:

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