



August 18, 2023

Shenzhen RF Tech Co., Ltd.  
% Gary Wang  
Quality & Regulation Director  
2-F, BLD4 Juhui Industrial Park  
Tianliao, Guangming  
Shenzhen, GD 518132  
CHINA

Re: K231085  
Trade/Device Name: 1.5T HD T/R Knee Array (10-F34127)  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: Class II  
Product Code: MOS  
Dated: July 24, 2023  
Received: July 24, 2023

Dear Gary 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'DK', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.  
Assistant Director  
DHT8C: Division of Radiological Imaging  
and Radiation Therapy Devices  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K231085

Device Name

1.5T HD T/R Knee Array (10-F34127)

Indications for Use (Describe)

The Knee Coil manufactured by Shenzhen RF Tech Co.,Ltd. is transmit/receive coil and is designed for use as general purpose coil. The Knee Coil is designed to be use with GEHC 1.5T MRI systems to produce diagnostic images of the knee, palm, sole, ankle, elbow, wrist 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.**

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## 510(k) Summary

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

I. Applicant/Manufacturer: Shenzhen RF Tech Co., Ltd.  
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Phone: (+86) 755-2664 1989-113  
Fax: (+86)755-2664 2989

Submitter/Correspondent: 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  
Contact Person: Mr. Gary Wang  
E-mail: gary.wang@rft.cn

### II. Device Regulation Information

Device Trade Name: 1.5T HD T/R Knee Array  
Classification panel: Radiology  
Classification Names: Magnetic Resonance Diagnostic Device  
Common Names: Coil, Magnetic Resonance, Specialty  
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: 10-F34127  
Device Trade Name: 1.5T HD T/R Knee Array

### IV. Predicate Device Information

Sponsor: Shenzhen RF Tech Co.,Ltd.  
Device: 8ch T/R Knee Coil  
510(K) Number: K223225

### V. Device Description

The 1.5T HD T/R Knee Array is transmit/receive phased array coil to produce diagnostic images of images of the knee, palm, sole, ankle, elbow, wrist.

The 1.5T HD T/R Knee Array 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. Indications for Use

The Knee Coil manufactured by Shenzhen RF Tech Co.,Ltd. is transmit/receive coil and is designed for use as general purpose coil. The Knee Coil is designed to be use with GEHC 1.5T MRI systems to produce diagnostic images of the knee, palm, sole, ankle, elbow, wrist that can be interpreted by a trained physician.

#### VII. Compatibility

The 1.5T HD T/R Knee Array is intended for use on 1.5T GE MRI. The 1.5T HD T/R Knee Array is compatible with GEHC 1.5T SIGNA Explorer System where coil ID allows.

#### VIII Technological Comparison

	Predicate Device	Subject	Result
K number	K223225		
Manufacturer	Shenzhen RF Tech Co.;Ltd.	Shenzhen RF Tech Co.,Ltd.	
Anatomical site	Knee, palm, sole, ankle, elbow, wrist	Knee, palm, sole, ankle, elbow, wrist	Same
Transmit/Receive	Transmit/Receive	Transmit/Receive	Same
Number of channels	8ch	8ch	Same
Field strength	1.5 T	1.5 T	Same
Preamplifier noise	0.5dB	0.5dB	Same
Energy Source	Scanner/DC 10V	Scanner/DC 10V	Same
Compatible systems	1.5T GE MRI	1.5T GE MRI	Equivalent
Coil design	phased array	phased array	Same
Tuning	Hydrogen (~64MHz)	Hydrogen (~64MHz)	Same
Decoupling method	active + passive	active + passive	Same
Patient-Contact	Surface-contacting	Surface-contacting	Same
Bio-compatibility Compliance	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

The proposed device has the same technological characteristics on design, energy source and using environment as the predicate device. The biocompatibility of material used is both compliance with ISO 10993-5 and ISO 10993-10.

#### IX. Summary of verification 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 performance;

2.IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for safety



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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.IEC 60601-2-33:2010+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.

Bench testing was conducted to demonstrate that image uniformity, SNR and coil surface heating met specified requirements. The test results also show that the 1.5T HD T/R Knee Array achieved the expected results and satisfied the standards listed above.

#### X. Conclusion:

Shenzhen RF Tech Co., Ltd. considers the 1.5T HD T/R Knee Array does not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.