



December 8, 2022

Shenzhen RF Tech Co., Ltd.
% Gary Wang
Q&R Consultant
Bonnier Quality Supervision Consulting (JM) Center
Hailunxinyuan No.3203, Jianghai District
Jiangmen City, Guangdong 529000
CHINA

Re: K223239
Trade/Device Name: 8ch Wrist Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: October 19, 2022
Received: October 20, 2022

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

510(k) Number (if known)

K223239

Device Name

8ch Wrist Coil

Indications for Use (Describe)

The 8ch Wrist Coil by Shenzhen RF Tech Co.,Ltd is receive-only coil and is designed for use as general purpose coil. The 8ch Wrist Coil is designed to be use with GE 1.5T MRI systems to produce diagnostic images of the wrists and fingers 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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K223239

Date:2022-12-08(YY-MM-DD)

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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Tianliao,Guangming,Shenzhen,
P.R.China 518132
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Submitter/Correspondent: Bonnier Quality Supervision Consulting (JM) Center
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Jiangmen City, China 529000
Phone: (+86) 13600366215

Contact Person: Mr. Gary Wang
Q&R Consultant
Email: gary.wang@bonnier.net.cn

II. Device Regulation Information

Common Name of Device: 8ch Wrist Coil
Classification panel: Radiology
Classification 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-F32119
Device Trade Name: 8ch Wrist Coil

IV. Predicate Device Information

Sponsor: MRI DEVICES CORPORATION
Device: HRW-63-8 WRIST ARRAY COIL;
HRW-127-8 WRIST ARRAY COIL

510(K) Number: K050622

V. Device Description



The 8ch Wrist Coil is receive only phased array coil to produce diagnostic images of the wrists and fingers in adult population.

The 8ch Wrist Coil 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.

The 8ch Wrist Coil is based on phased array technique to produce the images from 8 different channels with intergraded preamplifiers. The 8ch Wrist Coil is tuned to the proton frequency of 63.86MHz.

VI. Indications for Use

The 8ch Wrist Coil by Shenzhen RF Tech Co., Ltd. is receive-only coil and is designed for use as general purpose coil. The 8ch Wrist Coil is designed to be use with GE 1.5T MRI systems to produce diagnostic images of the wrists and fingers that can be interpreted by a trained physician.

VII. Compatibility

The connector of 8ch Wrist Coil is P-Port type. The 8ch Wrist Coil is compatible with GE1.5T MRI systems where coil ID allows.

VIII. Technological Comparison

Specification	Predicate Device	Subject	Result
K number	K050622	K223239	
Manufacturer	MRI DEVICES CORPORATION	Shenzhen RF Tech Co.,Ltd	
Indications for Use	To be used in conjunction with a magnetic resonance scanner to produce diagnostic images of the wrist and hand that can be interpreted by a trained physician.	The 8ch Wrist Coil manufactured by Shenzhen RF Tech Co.,Ltd is receive-only coil and is designed for use as general purpose coil. The 8ch Wrist Coil is designed to be use with GE 1.5T MRI systems to produce diagnostic images of the Wrists and fingers that can be interpreted by a trained physician.	Equivalent
Anatomical site	Wrist/Hand	Wrist/Fingers	Same
Transmit/Receive	RF coil (receive only)	RF coil (receive only)	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	GE 1.5T MRI systems	GE 1.5T MRI systems	Same



Coil design	phased array	phased array	Same
Tuning	Hydrogen (~64MHz)	Hydrogen (~64MHz)	Same
Decoupling method	Yes	Yes, active + passive	Same
Patient-contacting materials assessed for compliance with biocompatibility standards	Yes	Yes	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. ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] 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 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 8ch Wrist Coil achieved the expected results and satisfied the standards listed above.

X. Conclusion:

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