March 2, 2023

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

Re: K223203
Trade/Device Name: 1.5T 24E Posterior Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: February 1, 2023
Received: February 1, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K223203

Device Name
1.5T 24E POSTERIOR ARRAY

Indications for Use *(Describe)*
The 1.5T 24E Posterior Array by Shenzhen RF Tech Co., Ltd is receive-only coil and designed to be used with GE 1.5T MRI systems to produce diagnostic images of spine, when used with other coils, it also includes abdomen, torso, pelvis, prostate, cardiac, hips, and long bone imaging 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

Date:2023-03-02(YY-MM-DD)

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:	Bonnier Quality Supervision Consulting (JM) Center Hailunxinyuan No.3203, Jianghai District, 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	
Device Name:	1.5T 24E Posterior Array
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-F28808
Device Trade Name:	1.5T 24E Posterior Array
IV. Predicate Device Information	
Sponsor:	GE HANGWEI MEDICAL SYSTEMS CO., LTD.
Device:	BRIVO MR355, OPTIMA MR360
510(K) Number:	K123417

V. Device Description

The 1.5T 24E Posterior Array is receive only phased array coil to produce diagnostic images of Spine, when used with other coils, it also includes abdomen, torso, pelvis, prostate, cardiac, hips, and long bone.

The 1.5T 24E Posterior 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 1.5T 24E Posterior Array by Shenzhen RF Tech Co., Ltd is receive-only coil and designed to be use with GE 1.5T MRI systems to produce diagnostic images of spine, when used with other coils, it also includes abdomen, torso, pelvis, prostate, cardiac, hips, and long bone imaging that can be interpreted by a trained physician.

VII. Compatibility

The 1.5T 24E Posterior Array is compatible with GE 1.5T MRI systems where coil ID allows. The Compatibility with GE 1.5T MRI systems was verified.

VIII. Technological Comparison

	Predicate Device	Subject	Result
K number	K123417	K223203	
Manufacturer	GE HANGWEI MEDICAL SYSTEMS CO., LTD.	Shenzhen RF Tech Co.,Ltd	
Anatomical site	the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body.	Spine，When used with other coils, it also include abdomen, torso, pelvis, prostate, cardiac, hips, and long bone.	Equivalent
Transmit/Receive	RF coil (receive only)	RF coil (receive only)	Same
Number of channels	24 CH	24 CH	Same
Field strength	1.5T	1.5T	Same
Preamplifier noise	0.5dB	0.5dB	Same
Energy Source	Scanner	Scanner	Same
Compatible systems	GE 1.5T MRI	GE 1.5T MRI	Same
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 Subject 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 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 24E Posterior Array achieved the expected results and satisfied the standards listed above.

X. Summary of Clinical Tests:

In accordance with the FDA guidance document Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway, sample clinical images have been obtained with the 1.5T 24E Posterior Array from different anatomical sites and using various pulse sequences. The sample images obtained using the 1.5T 24E Posterior Array are of sufficient quality for diagnosis use.

XI. Conclusion:

Shenzhen RF Tech Co., Ltd. considers the 1.5T 24E Posterior Array does not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.