February 10, 2026

Shenzhen RF Tech Co., Ltd.
℅ Gary Wang
Consultant
Bonnier QM Consulting Center
Hailunxinyuan No.3203, Jianghai District
Jiangmen, GD 529000
China

Re: K252179
Trade/Device Name: GEM Flex Coil 16-L Array, 1.5T Receive Only;
GEM Flex Coil 16-M Array, 1.5T Receive Only;
GEM Flex Coil 16-S Array, 1.5T Receive Only
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: January 15, 2026
Received: January 15, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252179

Please provide the device trade name(s).

GEM Flex Coil 16-L Array, 1.5T Receive Only
GEM Flex Coil 16-M Array, 1.5T Receive Only
GEM Flex Coil 16-S Array, 1.5T Receive Only

Please provide your Indications for Use below.

The 1.5T GEM Flex Suite manufactured by Shenzhen RF Tech Co., Ltd. is receive-only coil and is designed for use as general-purpose coil. It includes of three coils: 16-L Array, 16-M Array, and 16-S Array. The 1.5T GEM Flex Suite is designed for use with GEHC 1.5T MRI systems to produce diagnostic images of the Head, Torso, Hip, Spine, Shoulder, Knee, Foot, Ankle, Elbow, and Wrist that can be interpreted by a trained physician.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K252179

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 QM Consulting 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 Trade Name:	GEM Flex Coil 16-L Array, 1.5T Receive Only GEM Flex Coil 16-M Array, 1.5T Receive Only GEM Flex Coil 16-S Array, 1.5T Receive Only
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/Trade Name:	10-F35780/GEM Flex Coil 16-L Array, 1.5T Receive Only 10-F35781/GEM Flex Coil 16-M Array, 1.5T Receive Only 10-F35782/GEM Flex Coil 16-S Array, 1.5T Receive Only

IV. Predicate Device Information

Sponsor:	GE HANGWEI MEDICAL SYSTEMS CO., LTD.
Device:	GEM Flex Coil, 1.5T
510(K) Number:	K113474

V. Device Description

The three Coils are receive only phased array coil to produce diagnostic images of the Head, Torso, Hip, Spine, Shoulder, Knee, Foot, Ankle, Elbow, and Wrist.

The three Coils are 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 GEM Flex Suite manufactured by Shenzhen RF Tech Co., Ltd. is receive-only coil and is designed for use as general-purpose coil. It includes of three coils: 16-L Array, 16-M Array, and 16-S Array. The 1.5T GEM Flex Suite is designed for use with GEHC 1.5T MRI systems to produce diagnostic images of the Head, Torso, Hip, Spine, Shoulder, Knee, Foot, Ankle, Elbow, and Wrist that can be interpreted by a trained physician.

VII. Compatibility

The connector of 1.5T GEM Flex Suite is P-Port. The 1.5T GEM Flex Suite with P-Port is compatible with GEHC 1.5T SIGNA Victor, SIGNA Prime Max and SIGNA Prime Elite, SIGNA Champion systems where coil ID allows. See the system documentation for details.

VIII Technological Comparison

	Predicate Device	Subject	Result
K number	K113474		
Manufacturer	MRI DEVICES CORP.	Shenzhen RF Tech Co.,Ltd	
Anatomical site	the Head, Torso, Hip, Spine, Shoulder, Knee, Foot, Ankle, Elbow, and Wrist	the Head, Torso, Hip, Spine, Shoulder, Knee, Foot, Ankle, Elbow, and Wrist	Same
Transmit/Receive	Receive only	Receive only	Same
Number of channels	16CH	16CH	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	GEHC 1.5T MRI systems	GEHC 1.5T MRI systems	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 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 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 GEM Flex Suite achieved the expected results and satisfied the standards listed above.

X. Conclusion:

Shenzhen RF Tech Co., Ltd. considers 1.5T GEM Flex Suite (GEM Flex Coil 16-L Array, 1.5T Receive Only; GEM Flex Coil 16-M Array, 1.5T Receive Only; GEM Flex Coil 16-S Array, 1.5T Receive Only) do not raise any new issues of safety or effectiveness, and performs as well as the legally marketed predicate device.

Date: 09-17-2025（MM-DD-YY）