March 20, 2026

Philips Healthcare (Suzhou) Co., Ltd.
Sherry Li
Regulatory Affairs Specialist
258, Zhongyuan Rd., Suzhou Industrial Park, Suzhou Jiangsu, China, 215024
Suzhou, Jiangsu 215024
China

Re: K260519
Trade/Device Name: Smart Fit TorsoCardiac 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: February 15, 2026
Received: February 17, 2026

Dear Sherry Li:

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,

NINGZHI LI -S Digitally signed by NINGZHI LI -S

for

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.	K260519

Please provide the device trade name(s).

Smart Fit TorsoCardiac 1.5T

Please provide your Indications for Use below.

The Smart Fit TorsoCardiac 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the torso (including chest, abdomen, and pelvis), cardiac, long bones, and neck that can be interpreted by a trained physician.

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

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

K260519

510(k) Summary

The 510(k) Summary was prepared in accordance with 21 CFR §807.92(c).

Preparation date: February 15, 2026

510(k) Owner:
Philips Healthcare (Suzhou) Co., Ltd.
No. 258, Zhongyuan Road,
Suzhou Industrial Park,
215024 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA
Establishment Registration Number: 3003768277

Contact person:
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Device Trade Name: Smart Fit TorsoCardiac 1.5T

Classification:
Regulation Description: Magnetic resonance diagnostic device
Regulation Number: 21 CFR 892.1000
Review Panel: Radiology
Device Class: Class II
Product Code: MOS

Predicate Device:
Trade name: Smart Fit TorsoCardiac 1.5T
510(k) Clearance: K232021
Manufacturer: Philips Healthcare (Suzhou) Co., Ltd.
Regulation Description: Magnetic resonance diagnostic device
Regulation Number: 21 CFR 892.1000
Review Panel: Radiology
Device Class: Class II
Product Code: MOS

Device description

The **Smart Fit Torsocardiac 1.5T** is a 16-channel phased array receive-only coil for high resolution diagnostic imaging of the torso (including chest, abdomen, and pelvis), cardiac, long bones, and neck. The coil foam is composed of PU foil, flexible PCB and EVA to provide sufficient flexibility along Left-Right direction for patient body scan. The layers from outside to patient side are: PU foil (outer surface),

EVA30 foam, PCBA of the coil and PU foil (inner surface). The foam looks flat at the top surface. A few parts, two feed-board boxes, cable housing and a small connector placed across the central Head-Feet axis are also at the top surface. Inner surface is naturally flat and is bendable along slots to fit well to the patient body.

Indications for use

The Smart Fit TorsoCardiac 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the torso (including chest, abdomen, and pelvis), cardiac, long bones, and neck that can be interpreted by a trained physician.

Comparison with the predicate device: The indications for Use statement provided above for the subject Smart Fit TorsoCardiac 1.5T is similar to the predicate device Smart Fit TorsoCardiac 1.5T (K232021). While the new indication for use statement of the subject device is modified to add anatomical locations “long bones”, remove “head”, and revise “heart” to “cardiac”. The applications on the new anatomical locations added in the Indications for Use statement have been verified and validated. Upon non-clinical and clinical test results of the subject device, no new safety and effectiveness issues were raised by the change of Indications for Use. The new indications for use of the subject device fall within the same intended use as that of the predicate device. Both the subject and predicate device have the same intended use and are intended to be used in conjunction with a 1.5T Magnetic Resonance Scanner to produce diagnostic images that can be interpreted by a trained physician.

Design Features/Fundamental Scientific Technology:

Same as the predicate device, the subject **Smart Fit TorsoCardiac 1.5T** is based on the principle that the coil receives magnetic resonance signals generated in hydrogen nuclei (protons) in the human body while blocking the radio frequency magnetic field applied by the MRI system at specified timings. The received signal is amplified and transmitted to the MRI system, where it is processed into tomographic images by the computer.

The subject device has similar technological characteristics that do not raise different questions of safety and effectiveness when compared to the manufacturer’s own marketed primary predicate device.

The following technological differences exist between the subject and predicate devices:

• The subject coil has slightly increased thickness and weight due to the redesigned coil PCBA layout and the addition of a new insulation foam pad. It also has more positioning marks on the front side.

• Different internal PCBA layout and external cable to enhance thermal performance and image quality.

Summary of Non-Clinical Performance Data

The Non-clinical performance testing has been performed on the subject **Smart Fit TorsoCardiac 1.5T** and demonstrates compliance with following international and FDA-recognized consensus standards

Recognition Number	Standard Number and Date	Standard Name
12-347	IEC 60601-2-33 Edition 4.0 2022-08	*Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*
19-46	ANSI / AAMI ES60601-1:2005/(R)2012 and A1:2012	*Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2006, MOD).*
19-36	IEC 60601-1-2:2014 [Including AMD 1:2021]	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]*
5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	*Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
5-129	IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	*Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1*
5-125	ISO 14971: 2019	*Medical devices – Application of risk management to medical devices*.
5-134	ISO 15223-1 Fourth Edition 2021-07	*Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*
12-188	MS-1-2008(R2020)	*Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging*
12-187	MS-3-2008(R2020)	*Determination of Image Uniformity in Diagnostic Magnetic Resonance Images*
12-288	MS-9-2008(R2020)	*Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images*
12-331	MS-14-2019	*Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems*
13-332	IEC 62464-1: 2018	*Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters.*

Non-Clinical verification and validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results.

The verification and/or validation test results demonstrate that the subject **Smart Fit TorsoCardiac 1.5T** meets the acceptance criteria and are adequate for the intended use.

The risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable.

Therefore, the subject **Smart Fit TorsoCardiac 1.5T** are substantially equivalent to the legally marketed predicate devices in terms of safety and effectiveness.

Summary of Clinical Data:

With the subject **Smart Fit TorsoCardiac 1.5T**, validation test results demonstrate that the subject Smart Fit TorsoCardiac 1.5T meets the acceptance criteria and are adequate for the updated Indications for Use. The subject device did not require clinical study since substantial equivalence to the legally marketed predicate device was proven in the comparison in terms of safety and effectiveness. All clinical images on the subject device **Smart Fit TorsoCardiac 1.5T** were evaluated by a by a U.S. Board Certified radiologist. No issue with the clinical image quality was seen and images were considered to have sufficient quality for diagnostic use.

Conclusion:

The subject **Smart Fit TorsoCardiac 1.5T** is substantially equivalent to the legally marketed predicate device *Smart Fit TorsoCardiac 1.5T* (K232021) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, substantial equivalence is demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards and device-specific guidance.

The results of these tests demonstrate that the subject **Smart Fit TorsoCardiac 1.5T** meet the acceptance criteria and are adequate for the intended use.