February 5, 2024

Philips Healthcare (Suzhou) Co., Ltd.
Sherry Li
Regulatory Affairs Specialist
No. 258, Zhongyuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
China

Re: K233600
Trade/Device Name: Smart Fit Knee 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: November 3, 2023
Received: November 9, 2023

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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

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.

Submission Number *(if known)*

K233600

Device Name

Smart Fit Knee 3.0T

Indications for Use *(Describe)*

The Smart Fit Knee 3.0T coil is designed to be used in conjunction with a Philips 3.0T MR system to produce diagnostic images of the Knee 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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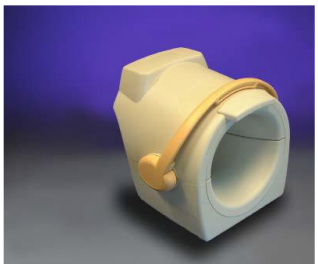
510(k) Summary
[As required by 21 CFR 807.92(c)]

Date Prepared:	November 09, 2023	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, Zhongyuan Road, Suzhou Industrial Park,Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630	
Primary Contact Person: **Secondary Contact Person**	Sherry Li Regulatory Affairs Specialist Phone: +86-0512-67336833 E-mail: sherry.li@philips.com Leo Louis Regulatory Affairs Director Phone: +31 (6) 87945888 E-mail: leo.louis@philips.com	
Device Name:	Smart Fit Knee 3.0T	
Classification:	Classification name:	Magnetic Resonance Diagnostic Device
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Magnetic Resonance Diagnostic Device
	Device Class:	Class II
	Primary Product Code:	MOS
Predicate Device for Smart Fit 3.0T	Trade name:	HRK-127-8 KNEE ARRAY COIL
	Manufacturer:	MRI Devices Corporation, 1515 Paramount Drive, Waukesha, Wisconsin 53186, U.S.A.
	510(k) Clearance:	K033567
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	MOS

Device Description:	The Smart Fit Knee 3.0T coil is designed to be used in conjunction with a Philips 3.0T MR system to produce diagnostic images of the Knee that can be interpreted by a trained physician. The Smart Fit Knee 3.0T is a 16-element coil designed for high-resolution imaging of the left or right knee. It is a phased-array, Rx volume coil providing an integrated solution with a base plate, an anterior and a posterior part. Positioning pads are also supplied to support comfortable positioning. The coil can be slightly rotated relative to its base plate to ease coil setup and enhance patient comfort. The coil is used independently and cannot be combined with any other coils. This coil is available for 3.0T MR systems and is compatible with Philips 3.0T MR Scanners.
Indications for Use:	The Smart Fit Knee 3.0T coil is designed to be used in conjunction with a Philips 3.0T MR system to produce diagnostic images of the Knee that can be interpreted by a trained physician.
Substantial Equivalence:	The 510(k) summary contains a summary of the technological characteristics of the proposed Smart Fit Knee 3.0T compared to the predicate devices HRK-127-8 KNEE ARRAY COIL (K033567).

Table 1

Comparison of the primary currently marketed and predicate device, HRK-127-8 KNEE ARRAY COIL versus the proposed Smart Fit Knee 3.0T

	Proposed Device, Smart Fit Knee 3.0T	**Primary Currently Marketed and Predicate Device, HRK-127-8 KNEE ARRAY COIL**	**Conclusion**
Design features			
Appearance			Similar. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Coil Dimensions Length X Width X Height	LXWXH = 538 X 280 X 293mm	LXWXH = 300 X 250 X 285mm	Similar. Smart Fit Knee 3.0T is designed to be assembled on a baseplate, so it's larger. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
Number of Channels /	16 Channels, 16 Preamplifiers	8 Channels, 8 Preamplifiers for	Similar.

	Preamplifiers		Trio 3.0T System. 6 Channels, 8 Preamplifiers for Philips Intera 3.0T system.	The differences in number of channels and preamplifiers between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
	System Connector / Compatibility and coil connector	Analogue connector mating face with dStream Interface 3.0T which has a DCI connector mating face with system.	Has a standard coil connector to connect the coil directly to an MRI system.	Similar. The differences between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
	Application site / body part	Knee.	Knee.	Same.
	Patient population	Philips Rx coils are intended for any patient who requires an MR examination, and for whom the use of the coil provides an additional diagnostic benefit (in terms of Field of View or Signal-to-noise ratio) according to the clinical user. Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to coil dimensions.	Intended for use on the order of a physician, in conjunction with a magnetic resonance (MR) scanner, as an accessory to produce images of the anatomy of interest, as an aid to diagnosis/ treatment.	Same. Although the wording is different, the meaning is the same. No difference in characteristics between products.
	Intended Use			
	Intended use	Philips Magnetic Resonance (MR) Receive-only (Rx) coils are intended to be used in conjunction with a Philips MR-system to enable trained physicians to obtain cross-sectional images of the internal structure of the head, body, or extremities, in any orientation. These images, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning.	To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the knee that can be interpreted by a trained physician.	Same. Although the wording is slightly different the meaning is the same. No difference in characteristics between products.
	Fundamental Scientific Technology			
	Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
	Magnetic Field Orientation	Head-Feet oriented	Head-Feet oriented	Same.

	(B0)			
	Frequency range	127.728MHz+/-0.75MHz	127.728MHz+/-0.75MHz	Same.
	Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Same.
	Energy source	Derived from MR scanner, no internal energy source	Derived from MR scanner, no internal energy source	Same.
	Housing Material	PC and PU.	Plastic.	Similar. PC is also a type of plastic. The safety of PC and PU has been proved in the biocompatibility report. The differences between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
	Base Pad	PCB	PCB	Same.
	Principle of operation	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 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.	Same.
	Biological characteristics Philips MR RF Rx coils are non-invasive surface devices that are only in contact with covered and/or intact patient skin with limited exposure (<24h). Biocompatibility testing against internal specifications and requirements of the ISO10993-1 has been performed. Further details can be found in the Biocompatibility Report.			
	Materials or substances in contact with which human tissues or body fluids*	Intact skin.	Intact skin.	Same.
	Kind and duration of contact with which human	Coils are in contact with covered and/or intact skin with limited exposure < 24h.	Coils are in contact with covered and/or intact skin with limited exposure < 24h.	Same.

	tissues or body fluids			
	Release characteristics of substances, including degradation products and leachables	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Same.
	* The characteristic must be the same for the demonstration of equivalence Based on the information provided above, Smart Fit Knee 3.0T are considered substantial equivalent to the primary currently marketed and predicate device HRK-127-8 KNEE ARRAY COIL (K033567).			
Summary of Non-Clinical Performance Data:	The proposed Smart Fit Knee 3.0T complies with the following international and FDA-recognized consensus standards: ● ANSI AAMI 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 FDA/CDRH recognition number 19-46 ● IEC60601-2-33 Ed. 3.2:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis FDA/CDRH recognition number 12-295 ● IEC0601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests FDA/CDRH recognition number 19-36 ● IEC60601-1-6:2010/AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA/CDRH recognition number 5-132 ● ISO 14971 Ed. 3:2019 Medical devices - Application of risk management to medical devices. FDA/CDRH recognition number 5-125. ● IEC 62366-1:2015/AMD1:2020 - Medical devices Part 1: Application of usability engineering to medical devices FDA/CDRH recognition number 5-129 ● ANSI AAMI ISO10993-1:2018 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process FDA/CDRH recognition number 2-258 ● NEMA MS 1-2008(R2020) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging FDA/CDRH recognition number 12-188 ● NEMA MS 3-2008 (R2020) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-187			

	• NEMA MS 9-2008 (R2020) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-288 • NEMA MS 14-2019 Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems FDA/CDRH recognition number 12-331 The performance test results demonstrate that the proposed Smart Fit Knee 3.0T meets the acceptance criteria and is adequate for its intended use. Additionally, 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. Based on the supporting data provided in this 510(k) submission, the proposed Smart Fit Knee 3.0T are considered substantially equivalent to the currently marketed and predicate device HRK-127-8 KNEE ARRAY COIL (K033567).
Summary of Clinical Data:	The proposed Smart Fit Knee 3.0T did not require clinical study since substantial equivalence to the legally marketed predicate device was demonstrated in comparison. All clinical images on the proposed coils Smart Fit Knee 3.0T were evaluated by qualified radiologists. No issues with the clinical image quality were seen and images were considered have sufficient quality for diagnostic use.