Philips Healthcare (Suzhou) Co., Ltd.
℅ Seaman Shao
Associate Regulatory Affairs Manager
No.258, ZhongYuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

December 1, 2021

Re: K212864
Trade/Device Name: dS TorsoCardiac 1.5T, dS MSK S 1.5T, dS MSK M 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: August 26, 2021
Received: September 8, 2021

Dear Seaman Shao:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212864

Device Name
dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T

Indications for Use *(Describe)*
The Magnetic Resonance (MR) coil is used with a Philips 1.5T MR scanner. A trained physician interprets the diagnostic images (of the anatomy of interest) produced.

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 K212864

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	August 26, 2021	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, ZhongYuan Road, Suzhou Industrial Park, Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630	
Primary Contact Person:	Seaman Shao Associate Regulatory Affairs Manager Phone: +86-13913116320 E-mail: seaman.shao@philips.com	
Secondary Contact Person	Erhong Wang Senior Regulatory Affairs Manager Phone: +86-13021019589 E-mail: erhong.wang@philips.com	
Device Name:	**dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T**	
Classification:	Classification Name:	Magnetic resonance diagnostic device
	Classification Regulation:	21CFR §892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product code:	MOS
Primary Predicate Device:	Trade Name:	(1) SENSE Torso 16 (2) SENSE MSK S 8CH 1.5T (3) 1.5T 8-CHANNEL MEDIUM GENERAL PURPOSE FLEX COIL
	Manufacturer:	Invivo Corporation
	510(k) Clearance:	(1) K122897, 21-12-2012 (2) K120122, 10-02-2012 (3) K111673, 23-12-2011

Classification Regulation:	21CFR §892.1000
Classification Name:	Magnetic resonance diagnostic device
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	MOS

Device description:

The proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T are designed to be used in conjunction with MR Scanner to produce diagnostic images of the anatomy of interest that can be interpreted by a trained physician.

The proposed dS TorsoCardiac 1.5T is a phased array receive-only coil for high resolution diagnostic imaging of torso, cardiac, 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.

The proposed dS MSK S 1.5T is a phased array receive-only coil for high resolution diagnostic imaging of wrist, foot-ankle, and elbow. 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, EVA 30 foam, and PU foil (inner surface). A few parts, 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.

The proposed dS MSK M 1.5T is a phased array receive-only coil for high resolution diagnostic imaging of shoulder, knee, hip, foot, and elbow. 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, EVA30 foam, and PU foil (inner surface). A few parts, 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.

The proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T are designed to be used with the Philips 1.5T MRI Scanners.

Indications for Use:

The indications for use for the proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T are as follows:

The Magnetic Resonance (MR) coil is used with a Philips 1.5T MR scanner. A trained physician interprets the diagnostic images (of the anatomy of interest) produced.

Fundamental Scientific Technology:

The 510(k) summary contains a summary of the technological characteristics of the proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T compared to the predicate devices

Attribute	Predicate Device, SENSE Torso 16	Proposed dS TorsoCardiac 1.5T
Fundamental Scientific Technology		
Type of coil	Phased-array Receive only coil	Identical
Magnetic Field Orientation (B0)	Head-Feet oriented	Identical
Frequency range	63.87MHz+/-0.75MHz	Identical
Housing Material	PC and PU	Identical

Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Identical
Energy source	Derived from MR scanner, no internal energy source	Identical
Workflow to support the connection and signal transmission between the coil and MR system	The coil cable connects to MR system tabletop via coaxial and DC pins mixed analogue connector to fit any intended coil position on tabletop according to the needs of MR scan.	The coil cable connects to dS Interface S 1.5T or dS Interface L 1.5T, which is connected into DCI of MR system tabletop, via a DCI connector with coaxial pins to fit any intended coil position on tabletop according to the needs of MR scan. No impact to device safety and effectiveness since it only provides a better workflow.
Flexibility of coil to ensure well fit to patient body	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, whereas it is rigid in Head-Feet direction due to the existing of long rigid PCBAs and baluns along this direction.	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, and the coil offers a degree of flexibility along the Head-Feet direction since the baluns are moved to the coil cable and the size of rigid PCBAs are decreased. No impact to device safety and effectiveness since it

		only provides a better flexibility and workflow.
Easily removeable structure to support the serviceability of coil	The baluns and one of rigid PCBA are centralized in the middle of coil, and a removeable plastic cover is designed to cover them, whereas the other rigid PCBAs can be repaired or replaced only after the entire coil foam is disassembled.	All rigid PCBAs are placed at the left and right side of coil, and two removeable plastic covers are designed to cover them, meanwhile the baluns are covered by plastic housings in the coil cable, and they can be also repaired or replaced by removing housings. No impact to device safety and effectiveness since it only provides a better serviceability.

Attribute	**Predicate Device,** **SENSE MSK S 8CH 1.5T**	**Proposed dS MSK S 1.5T**
Fundamental Scientific Technology		
Type of coil	Phased-array Receive only coil	Identical

Magnetic Field Orientation (B0)	Head-Feet oriented	Identical
Frequency range	63.87MHz+/-0.75MHz	Identical
Housing Material	PC and PU	Identical
Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Identical
Energy source	Derived from MR scanner, no internal energy source	Identical
Workflow to support the connection and signal transmission between the coil and MR system	The coil cable connects to MR system tabletop via coaxial and DC pins mixed analogue connector to fit any intended coil position on tabletop according to the needs of MR scan.	The coil cable connects to dS Interface S 1.5T or dS Interface L 1.5T, which is connected into DCI of MR system tabletop, via a DCI connector with coaxial pins to fit any intended coil position on tabletop according to the needs of MR scan. No impact to device safety and effectiveness since it only provides a better workflow.

Flexibility of coil to ensure well fit to patient body	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, whereas it is rigid in Head-Feet direction due to the existing of long rigid PCBAs and baluns along this direction.	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, and the coil offers a degree of flexibility along the Head-Feet direction since the baluns are moved to the coil cable and the size of rigid PCBAs are decreased significantly. No impact to device safety and effectiveness since it only provides a better flexibility and workflow.

Attribute	**Predicate Device, 1.5T 8-CHANNEL MEDIUM GENERAL PURPOSE FLEX COIL**	**Proposed dS MSK M 1.5T**
Fundamental Scientific Technology		
Type of coil	Phased-array Receive only coil	Identical
Magnetic Field Orientation (B0)	Head-Feet oriented	Identical
Frequency range	63.87MHz+/-0.75MHz	Identical
Housing Material	PC and PU	Identical

Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Identical
Energy source	Derived from MR scanner, no internal energy source	Identical
Workflow to support the connection and signal transmission between the coil and MR system	The coil cable connects to MR system tabletop via coaxial and DC pins mixed analogue connector to fit any intended coil position on tabletop according to the needs of MR scan.	The coil cable connects to dS Interface S 1.5T or dS Interface L 1.5T, which is connected into DCI of MR system tabletop, via a DCI connector with coaxial pins to fit any intended coil position on tabletop according to the needs of MR scan. No impact to device safety and effectiveness since it only provides a better workflow.
Flexibility of coil to ensure well fit to patient body	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, whereas it is rigid in Head-Feet direction due to the existing of long rigid PCBAs and baluns along this direction.	The coil foam is composed of PU foil, flexible PCBA and EVA to provide sufficient flexibility along the Left-Right direction for patient body scan, and the coil offers a degree of flexibility along the Head-Feet direction since the baluns are moved to the coil cable and the size of rigid PCBAs are decreased significantly. No impact to device safety and effectiveness since it

		only provides a better flexibility and workflow.

Based on the information provided above, dS TorsoCardiac 1.5T is considered substantially equivalent to the primary currently marketed and predicate device SENSE Torso 16 (K122897, 21-12-2012) in terms of fundamental scientific technology

Based on the information provided above, dS MSK S 1.5T is considered substantially equivalent to the primary currently marketed and predicate device SENSE MSK S 8CH 1.5T (K120122, 10-02-2012) in terms of fundamental scientific technology

Based on the information provided above, dS MSK M 1.5T is considered substantially equivalent to the primary currently marketed and predicate device 1.5T 8-CHANNEL MEDIUM GENERAL PURPOSE FLEX COIL (K111673, 23-12-2011) in terms of fundamental scientific technology

Summary of Non-Clinical Performance Data:

The proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T complies with the following international and FDA-recognized consensus standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements. For Basic Safety And Essential Performance (IEC 60601-1:2012, MOD)
  FDA/CDRH recognition number 19-4
- 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
- IEC60601-1-2 Ed. 4.0:2014 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 19-8
- ISO 14971 Ed. 2.0:2007 Medical devices – Application of risk management to medical devices.
  FDA/CDRH recognition number 5-40.

- Magnetic Resonance (MR) Receive only Coil – Performance Criteria for Safety and Performance Based Pathway - issued on December 11, 2020
- Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued June 16, 2016 – document number 1811)
- IEC 62366 Edition 1.1: 2014-01 Medical devices – Application of usability engineering to medical devices
  FDA/CDRH recognition number 5-87
- NEMA MS 1-2008(R2020)
  Determination of Signal-to-Noise Ratio (SNR)
  in Diagnostic Magnetic Resonance Imaging
- NEMA MS 3-2008 (R2020)
  Determination of Image Uniformity
  in Diagnostic Magnetic Resonance Images
- NEMA MS 9-2008 (R2020) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- NEMA MS 14-2019 Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

There are no risks identified in risk management documentation that require clinical data for the purpose of clinical evaluation; Risk Management Plan as Appendix 001, Risk Management Report as Appendix 002, and Risk Management Matrix as Appendix 003 of dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T.

Sufficient evidence is available to demonstrate the ability of dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T achieve the intended performances during normal condition of use;

Full consistency exists between the state-of-the-art, the evaluated data, the risk management documentation and the information materials supplied.

Therefore, the proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T are substantially equivalent to the primary currently marketed and predicate device SENSE Torso 16 (K122897, 21-12-2012), SENSE MSK S 8CH 1.5T (K120122, 10-02-2012) and 1.5T 8-CHANNEL MEDIUM GENERAL PURPOSE FLEX COIL (K111673, 23-12-2011) in terms of safety and effectiveness.

Summary of Clinical Data:

The proposed dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T do not require clinical study since substantial equivalence to the predicate device was demonstrated with the following attributes:

- Design features.
- Fundamental scientific technology
- Indications for use;
- Safety and effectiveness
- Non-clinical performance testing;

Substantial Equivalence Conclusion:

The dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T are substantially equivalent to the primary currently marketed and predicate device SENSE Torso 16, SENSE MSK S 8CH 1.5T, 1.5T 8-CHANNEL MEDIUM GENERAL PURPOSE FLEX COIL in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance tests, which complied with the requirements specified in the international and FDA-recognized consensus standards. The results of these tests demonstrate that dS TorsoCardiac 1.5T, dS MSK S 1.5T and dS MSK M 1.5T met the acceptance criteria and are adequate for this intended use.