January 14, 2026

Philips Medical Systems Nederland BV
Ketaki Bendre
Regulatory Affairs Manager
Veenpluis 6
Best, 5684 PC
Netherlands

Re: K254190
Trade/Device Name: dS Base 1.5T; dS Base 3.0T; dS Head 1.5T; dS Head 3.0T; dS HeadNeck 1.5T; dS HeadNeck 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: December 23, 2025
Received: December 23, 2025

Dear Ketaki Bendre:

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.

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.01.14 14:53:37 -05'00'

For

Daniel Krainak
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254190

Device Name
dS Base 1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T, dS HeadNeck 3.0T.

Indications for Use *(Describe)*
The Philips Neurovascular MR Coil is intended to be used in conjunction with a Philips 1.5T or 3T Magnetic Resonance Scanner to produce diagnostic images of the anatomy of interest 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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K254190

510(k) Summary

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

Preparation date:	January 12, 2026	
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration Number: 3042177665	
Contact person:	Ketaki Bendre (Primary Contact) Regulatory Affairs Manager Philips Medical Systems Nederland B.V. Email: ketaki.bendre@philips.com Swapnil Jain (Secondary Contact) Senior Regulatory Affairs Manager Philips Medical Systems Nederland B.V. Email: swapnil.jain@philips.com	
Device Trade Name:	dS Base 1.5T, dS Base 3, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T, dS HeadNeck 3.0T	
Classification:	**Classification Name:**	Coil, Magnetic Resonance, Specialty
	Regulation Number:	21 CFR 892.1000
	Review Panel:	Radiology
	Device Class:	Class II
	Product Code:	MOS
Predicate Device:	**Trade name:**	dS Base 1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS. Head-Neck 1.5T, dS Head-Neck 3.0T
	510(k) Clearance:	K123492
	Manufacturer:	Philips Medical Systems Nederland B.V.
	Classification Name:	Coil, Magnetic Resonance, Specialty
	Regulation Number:	21 CFR 892.1000
	Review Panel:	Radiology
	Device Class:	Class II
	Product Code:	MOS
Reference Device:	**Trade name:**	dS Sentinelle Breast 16 Ch Coil
	510(k) Clearance:	K213735
	Manufacturer:	Philips Medical Systems Nederland B.V.
Reference Device:	**Trade name:**	dS FootAnkle 16 Ch Coils

510(k) Clearance: K213766
Manufacturer: Philips Medical Systems Nederland B.V.

Device description

A general description of the subject devices, which are part of the Philips Neurovascular MR Coil Family is given below:
The **dS Base 1.5T** and **dS Base 3.0T** are lightweight, 8-channel, phased-array coil that are designed to be used independently or in combination with the dS Head or dS HeadNeck coil. The dS Base coil also can be used for extremities and pediatric examinations or can be combined with the dS Posterior coil which is integrated in the patient support of the compatible Magnetic Resonance (MR) Systems for total spine imaging. The dS Base coil can stay on the table for most examinations without exchanging coils, thereby, improving workflow. These coils are connected to the flex connect socket of the compatible MR System.

The **dS Head 1.5T** and **dS Head 3.0T** are 7-channel receive only coils, which are designed to be used in combination with the dS Base (bottom) coil to create a 15-channel coil with or without the dS Posterior coil which is integrated in the patient support of the compatible MR Systems for total spine imaging. The coil is most frequently used for imaging the head/brain and its vasculature. The coil can also be used for extremities and pediatric examinations. These coils are available in both 1.5T and 3.0T and are connected to the flex connect socket of the compatible MR System.

The **dS HeadNeck 1.5T** and **dS HeadNeck 3.0T** are 8-channel receive only coils, which are designed to be used in combination with the dS Base (bottom) coil to create a 16-channel coil with or without the dS Posterior coil which is integrated in the patient support of the compatible MR Systems for total spine imaging. The coil is used for brain, head, neck, cervical spine, and neurovascular imaging. The coil also can be used for extremities and pediatric examinations. These coils are available in both 1.5T and 3.0T and are connected to the flex connect socket of the compatible MR System

The dS HeadNeck coil can be used either alone or in combination with the dS Anterior coil and dS Posterior coil. When used in combination with the dS Anterior coil and dS Posterior coil for Whole Body exams this is called a ‘Whole Body solution.

Indications for use

The indications for Use statement provided below for the subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** is similar to the predicate *device* ***dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS Head-Neck 1.5T and dS Head-Neck 3.0T*** (K123492). While the new indication for use statement of the subject device is modified to make the wording specific for the subject device coils. The difference in wording in the Indications for Use statement do not raise any new safety and effectiveness questions, both devices have the same intended use and are intended to be used in conjunction with a MR Scanner to produce diagnostic images of the anatomy of interest that can be interpreted by a trained physician.

The Philips Neurovascular MR Coil is intended to be used in conjunction with a Philips 1.5T or 3T Magnetic Resonance Scanner to produce diagnostic images of the anatomy of interest that can be interpreted by a trained physician.

Design Features/Fundamental Scientific Technology:

Same as the predicate device, the subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** 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 principal technological components (PCBs, system cable, baluns and positioning/comfort pads) of the subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** is unchanged compared to predicate device.

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

• The subject device housing material has changed from polyester (Trirex) in predicate device to polycarbonate (Lexan 925) for dS Base coils.

• The subject device housing material has changed from polyester (Trirex) in predicate device to copolyester (MFX-421) for dS Head /dS HeadNeck coils

Summary of Non-Clinical Performance Data

The Non-clinical performance testing has been performed on the subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** 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)]*

2-258	ISO 10993-1:2018	ISO 10993-1:2018 - Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
2-291	10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
2-245	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-296	10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
5-129	ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	*Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1*
5-125	ANSI AAMI ISO 14971: 2019	*Medical devices – Application of risk management to medical devices*.
5-134	ISO 15223-1:2021, 15223-1 Fourth Edition 2021-07	*Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*
5-126	ISTA 3A 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
14-579	17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

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 **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** meet 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 **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** are substantially equivalent to the legally marketed predicate devices in terms of safety and effectiveness.

Summary of Clinical Data:

With the subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T**, the indications for use remain similar and there were no technological characteristics relative to the predicate device that would require clinical testing.

Conclusion:

The subject **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0T** are substantially equivalent to the legally marketed predicate device *dS Base1.5T, dS Bae 3.0T, dS Head 1.5T, dS Head 3.0T, dS Head-Neck 1.5T and dS Head-Neck 3.0T* (K123492) 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 **dS Base1.5T, dS Base 3.0T, dS Head 1.5T, dS Head 3.0T, dS HeadNeck 1.5T and dS HeadNeck 3.0** meet the acceptance criteria and are adequate for the intended use.