July 30, 2026

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

Re: K262330
Trade/Device Name: dS Breast 7ch 1.5TdS Breast 7ch 3.0TdS Breast 16ch 1.5TdS Breast 16ch 3.0TdS Breast Coil 7ch 1.5TdS Sentinelle Breast 16ch 1.5TdS Sentinelle Breast 16ch 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: July 8, 2026
Received: July 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.	K262330

Please provide the device trade name(s).

dS Breast 7ch 1.5T
dS Breast 7ch 3.0T
dS Breast 16ch 1.5T
dS Breast 16ch 3.0T
dS Breast Coil 7ch 1.5T
dS Sentinelle Breast 16ch 1.5T
dS Sentinelle Breast 16ch 3.0T

Please provide your Indications for Use below.

dS Breast Coil 7ch 1.5T
The dS Breast Coil 7ch 1.5T is intended to be used in conjunction with a Philips Prodiva 1.5T CS, Prodiva 1.5T CX, and a MR 5300 1.5T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Breast 7ch 1.5T/3.0T
The Philips dS Breast 7ch 1.5T & 3.0T Coil is to be used in conjunction with a Philips 1.5T & 3.0T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Breast 16ch 1.5T/3.0T
The Philips dS Breast 16ch 1.5T & 3.0T Coil is to be used in conjunction with a Philips 1.5T & 3.0T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Sentinelle 16ch 1.5T/3.0T
The dS Sentinelle 16ch 1.5T & 3.0T Coil for Philips Ingenia 1.5T & 3.0T MRI Systems are designed to provide magnetic resonance images of breast anatomy when used in conjunction with a magnetic resonance scanner in adult and adolescent patients. A trained physician interprets these images. When used with a disposable biopsy grid, the coil permits access to breast anatomy for biopsy and localization procedures.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary K262330

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

Preparation date: July 21, 2026

510(k) Owner:
Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
Establishment Registration Number: 3042177665

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	Device(s)	**Predicate Device(s)**
Trade Name:	dS Breast Coil 7ch 1.5T	dS Breast Coil 7ch 1.5T - K232762
	dS Breast 7ch 1.5T	Model BBC Biopsy Breast Coil - K032576
	dS Breast 7ch 3.0T	Model BBC-127-ACHIEVA Biopsy Breast Coil - K041481
	dS Breast 16ch 1.5T dS Breast 16ch 3.0T	LBS-63-16 Breast Array Coil - K072873
	dS Sentinelle Breast 16ch 1.5T	dS Sentinelle Breast 16ch 1.5T - K213735

	dS Sentinelle Breast 16ch 3.0T	dS Sentinelle Breast 16ch 3.0T - K213727
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 1	**Reference Device 2**
Trade name:	dS Shoulder 8ch 1.5T Coil - K222325	dS Breast Coil 7ch 1.5T - K232762
Manufacturer:	Philips Medical Systems Nederland B.V.	

Device description

dS Breast Coil 7ch 1.5T

The dS Breast coil 7ch 1.5T is a receive-only, 7-element phased array radiofrequency (RF) coil intended for use with compatible 1.5T magnetic resonance imaging (MRI) systems. The coil is used independently and cannot be combined with other coils. The coil is designed to operate in conjunction with the MRI system body coil, which provides RF transmission, while the coil receives the resultant RF signals. The open coil design facilitates patient positioning and supports both diagnostic breast imaging and interventional breast procedures, including biopsy, when used with appropriate accessories.

dS Breast 7ch 1.5T and 3.0T

The dS Breast 7ch 1.5T and 3.0T is a receive-only, 7-element phased array RF coil intended for use with compatible 1.5T and 3.0T MRI systems. The coil is used independently and cannot be combined with other coils. The coil operates in conjunction with the MRI system body coil for RF transmission and is designed with an open architecture to support patient positioning for diagnostic breast imaging and interventional breast procedures, including biopsy, when used with appropriate accessories.

dS Breast 16ch 1.5T and 3.0T

The dS Breast 16ch 1.5T and 3.0T is a receive-only, 16-element phased array RF coil intended for use with compatible 1.5T and 3.0T MRI systems. The coil is used independently and cannot be combined with other coils.

dS Sentinelle Breast 16ch 1.5T and 3.0T

The dS Sentinelle Breast 16ch 1.5T and 3.0T coil includes a tabletop patient support and receive-only phased array RF imaging coils designed to enable diagnostic breast imaging and interventional device guidance for biopsy and localization procedures. The tabletop provides access to the breasts to facilitate imaging and interventional procedures. The dS Sentinelle Breast 16ch can be used in multiple channel (2, 10, or 16) configurations to support diagnostic imaging and interventional access, depending on the clinical application.

Indications for use

dS Breast Coil 7ch 1.5T

The dS Breast Coil 7ch 1.5T is intended to be used in conjunction with a Philips Prodiva 1.5T CS, Prodiva 1.5T CX, and a MR 5300 1.5T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Breast 7ch 1.5T/3.0T

The Philips dS Breast 7ch 1.5T & 3.0T Coil is to be used in conjunction with a Philips 1.5T & 3.0T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Breast 16ch 1.5T/3.0T

The Philips dS Breast 16ch 1.5T & 3.0T Coil is to be used in conjunction with a Philips 1.5T & 3.0T Magnetic Resonance Scanner in adult and adolescent patients to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

dS Sentinelle 16ch 1.5T/3.0T

The dS Sentinelle 16ch 1.5T & 3.0T Coil for Philips Ingenia 1.5T & 3.0T MRI Systems are designed to provide magnetic resonance images of breast anatomy when used in conjunction with a magnetic resonance scanner in adult and adolescent patients. A trained physician interprets these images. When used with a disposable biopsy grid, the coil permits access to breast anatomy for biopsy and localization procedures.

The indications for Use statements for the subject devices are not identical to those of the predicate devices; however, the differences do not alter the intended diagnostic use of the devices, nor do they affect the safety and effectiveness of the devices relative to the predicate devices. Both the subject and predicate devices have the same intended use, namely, 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.

Design Features/Fundamental Scientific Technology

Magnetic resonance imaging using receive-only radiofrequency (RF) coils is the technological principle for both the subject and predicate devices. This principle is based on the use of dedicated RF coil elements to receive magnetic resonance signals generated in hydrogen nuclei within the human body during MRI examinations, which are subsequently processed by the MRI system to generate diagnostic images.

At a high level, the subject and predicate devices are based on the same technological elements, including:

- Receive-only phased array RF coil elements used in conjunction with an MRI system body coil for RF transmission,
- Use with compatible 1.5T and/or 3.0T magnetic resonance scanners,
- Acquisition of MR signals for diagnostic imaging of breast anatomy,
- Coil housings and patient interfaces designed to allow positioning and stabilization of the breasts,
- Use of the MRI system for signal processing and image reconstruction.

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

- Limited material changes to non-active components,
- Updates to mechanical design and patient interface components,
- Modifications to system compatibility with specific MRI platforms,
- Introduction of additional coil configuration within the same device family.
- The IFU of the subject devices have been updated to improve clarity, alignment with current clinical use, and consistency with applicable Philips MR System documentation. In addition, a new warning regarding use in patients with compromised bone strength has been added.

These differences do not alter the fundamental scientific technology of the devices and do not raise new questions of safety or effectiveness relative to the predicate devices.

Summary of Non-Clinical Performance Data

Non-clinical verification and validation testing was performed with respect to the intended use, the technical claims, the design requirements and risk management activities for the subject devices.

Testing was conducted in accordance with applicable FDA-recognized consensus standards and considered the recommendations in applicable FDA guidance documents, including *Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices* (document number GUI00000340, issued October 10, 2023), and *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway* (document number 19011, issued December 11, 2020).

The performance test categories summarized below, including image signal-to-noise ratio, image uniformity, surface heating, acquired image quality, decoupling circuit functionality, electromagnetic compatibility, and general electrical/mechanical safety, were selected consistently with the recommendations in the FDA MR receive-only coil performance criteria guidance.

Test category	Standard/guidance	Summary of testing	Result
Labeling verification	ISO 20417, as applicable Risk management and IFU verification activities; applicable FDA MR guidance recommendations	IFU reviewed for applicable risk-control measures, including contraindications, limitations, warnings, precautions, positioning instructions, cleaning/disinfection instructions, compatible MR system documentation, and anatomy of interest.	Passed; applicable labeling risk-control measures were present.
Image signal-to-noise ratio	NEMA MS 9; NEMA MS 1; FDA MR receive-only coil performance criteria guidance	SNR testing performed for applicable 1.5T and 3.0T configurations.	Passed; lowest measured SNR values exceeded predefined acceptance criteria.
Image uniformity	NEMA MS 9; NEMA MS 3; FDA MR receive-only coil performance criteria guidance	Image uniformity testing performed for applicable subject devices.	Passed; worst-case non-uniformity was below the specified limit.
Essential image quality parameters	IEC 62464-1, as applicable	Essential image quality parameters evaluated, as applicable.	Passed; predefined acceptance criteria were met.
Decoupling circuit functionality	FDA MR receive-only coil performance criteria guidance; internal functional specification	Functional verification confirmed preamplifier decoupling for each RF channel.	Passed; predefined acceptance criteria were met.
Cleaning and disinfection	ISO 17664, as applicable	Cleaning and disinfection validation supported the reprocessing instructions.	Passed; predefined acceptance criteria were

Test category	Standard/guidance	Summary of testing	Result
			met.
Biocompatibility	ISO 10993-1; ISO 10993-5, as applicable; FDA biocompatibility guidance recommendations	Biological evaluation considered surface contact with intact skin and applicable endpoints, including cytotoxicity, sensitization, and irritation. Cytotoxicity testing was performed for applicable housing material changes.	Passed; patient-contacting materials were biocompatible for the intended contact type and duration.
Acquired image quality	FDA MR receive-only coil performance criteria guidance	Sample images from target anatomical locations were assessed for diagnostic quality by a U.S. board-certified radiologist.	Passed; images were attested to be of sufficient quality for diagnostic use.
EMC – Immunity, electrostatic discharge	IEC 60601-1-2, IEC 61000-4-2, as applicable FDA MR receive-only coil performance criteria guidance	EMC performance evaluated for subject devices	Passed; predefined acceptance criteria were met.
General electrical/mechanical safety	AAMI/ANSI ES60601-1, IEC 60601-2-33, as applicable FDA MR receive-only coil performance criteria guidance	Electrical/mechanical safety performance evaluated for subject devices	Passed; device demonstrated safe performance, as anticipated in its intended use environment.
Surface heating	NEMA MS 14 FDA MR receive-only coil performance criteria guidance	Surface heating was evaluated as per temperature criteria defined by ANSI/AAMI ES 60601-1	Passed; surface temperature for normal use and single fault condition was less than 41°C.

Biocompatibility data from the legally marketed reference device dS Shoulder 8ch 1.5T Coil (K222325) were leveraged to support the biocompatibility assessment of the LEXAN™ 950 housing material used in the dS Breast 16ch 1.5T and dS Breast 16ch 3.0T subject devices. The subject and reference devices use the same LEXAN™ 950 housing material and have the same nature and duration of patient contact, namely surface contact with intact skin. Therefore, the established biocompatibility information for the reference device supports the biocompatibility assessment of the LEXAN™ 950 housing material in these subject devices.

Biocompatibility data from the legally marketed reference device dS Breast Coil 7ch 1.5T (K232762) were leveraged to support the biocompatibility assessment of the L&K Foil padding material used in the dS Breast 7ch 1.5T, dS Breast 7ch 3.0T, dS Breast 16ch 1.5T, and dS Breast 16ch 3.0T subject devices. The subject and reference devices use the same L&K Foil padding material and have the same nature and duration of patient contact, namely surface contact with intact skin. Therefore, the established biocompatibility information for the reference device supports the biocompatibility assessment of the L&K Foil padding material in these subject devices.

Conclusion

The predefined acceptance criteria for all verification and validation testing were met. The results demonstrate that the subject devices perform as intended, are adequate for their intended use, and support a determination of substantial equivalence to the legally marketed predicate devices in terms of safety and effectiveness.

Summary of Clinical Data

Clinical testing was not required to support a determination of substantial equivalence because the indications for use of the subject devices remain similar to those of the predicate devices and there are no differences in technological characteristics that would raise new questions of safety or effectiveness.

Conclusion

Based on a comparison of indications for use, technological characteristics, and non-clinical performance data, the subject devices are substantially equivalent to the legally marketed predicate devices with respect to design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Non-clinical performance testing demonstrated that the subject devices perform as intended and are adequate for their intended use, thereby supporting the determination of substantial equivalence.