July 24, 2026

Philips Medical Systems Nederland B.V.
K Jeevan Kumar Reddy
Regulatory Affairs Manager
Veenpluis 6, 5684 Pc Best
Best, 5684PC
Netherlands

Re: K262294
Trade/Device Name: dS FootAnkle 16Ch 1.5T;dS FootAnkle 16Ch 3.0T;dS HiRes Hand/Wrist 16Ch 1.5T;dS HiRes Hand/Wrist 16CH 3.0T;dS Small Extremity 16Ch 1.5T;dS Small Extremity 16Ch 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: July 7, 2026
Received: July 7, 2026

Dear K Jeevan Kumar Reddy:

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, PhD
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)*
K262294

Device Name
dS Small Extremity 16Ch 1.5T and dS Small Extremity 16Ch 3.0T

Indications for Use *(Describe)*
The dS Small Extremity 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the small extremities anatomy in neonate, infant, children, adolescent and adult patients 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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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)*
K262294

Device Name
dS HiRes Hand/Wrist 16Ch 1.5T and dS HiRes Hand/Wrist 16Ch 3.0T

Indications for Use *(Describe)*
The dS HiRes Hand/Wrist 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the hand and wrist anatomy in adolescent and adult patients 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)

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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)*
K262294

Device Name
dS FootAnkle 16Ch 1.5T and dS FootAnkle 16Ch 3.0T

Indications for Use *(Describe)*
The dS FootAnkle 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the foot and ankle anatomy in adolescent and adult patients 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)

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510(k) Summary

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

Preparation date:	July 23, 2026
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration Number: 3042177665
Contact person:	Jeevan Kumar Reddy (Primary Contact) Regulatory Affairs Manager Philips Medical Systems Nederland B.V. Email: JeevanKumar.Reddy@philips.com Mobile: +91 9600239983 Swapnil Jain (Secondary Contact) Senior Regulatory Affairs Manager Philips Medical Systems Nederland B.V. Email: swapnil.jain@philips.com
Device Trade Name:	dS FootAnkle 16Ch 1.5T, dS FootAnkle 16Ch 3.0T, dS HiRes Hand/Wrist 16Ch 1.5T, dS HiRes Hand/Wrist 16Ch 3.0T, dS Small Extremity 16Ch 1.5T and dS Small Extremity 16Ch 3.0T
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 FootAnkle 16Ch 1.5T, dS FootAnkle 16Ch 3.0T, dS HiRes Hand/Wrist 16Ch 1.5T, dS HiRes Hand/Wrist 16Ch 3.0T, dS Small Extremity 16Ch 1.5T and dS Small Extremity 16Ch 3.0T (K213766)
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

Device description

dS FootAnkle 16Ch 1.5T and 3.0T

The dS FootAnkle 16Ch is a 16-element, ski-boot shaped, receive-only coil designed for dStream MR systems. The coil is designed to provide optimum coverage and high-resolution visualization of detailed cartilage structures in the ankle and entire foot up to the toes, including larger foot sizes. The patient's foot can be positioned vertically or at a comfortable angle of up to 20 degrees plantar flexed towards the sole. These coils can be tilted in vertical position to further improve patient comfort. The coil is used independently and is not intended to be combined with other coils. The coil is available for both 1.5T and 3.0T MR systems.

dS HiRes Hand/Wrist 16Ch 1.5T and 3.0T

The dS HiRes Hand/Wrist 16Ch is a 16-element receive-only coil designed for dStream MR systems. The coil is designed to visualize the thin cartilage layers and the interosseous ligaments of the hand and wrist. The coil can be used vertically at the patient's side or horizontally overhead, connected to a rigid base plate for fixation to reduce patient motion. The coil is available for both 1.5T and 3.0T MR Systems. The coil is used independently and is not intended to be combined with other coils.

dS Small Extremity 16Ch 1.5T and 3.0T

The dS Small Extremity 16Ch is a 16-element receive-only coil designed for dStream MR systems and accommodates various patient sizes. The coil has an inner diameter of 20 cm to match the size of small extremities such as elbows, wrists, hands, small knees, ankles and shoulders. The coil has a close fit to the anatomy enabling high resolution imaging of cartilage and bone. The flexible wrap-around design supports easy positioning and a secure fit. A dedicated mattress that supports both patient and coil is included to improve patient comfort and reduce motion. The coil is used independently and is not intended to be combined with other coils. The coil is available for both 1.5T and 3.0T MR Systems.

Indications for use

dS FootAnkle 16Ch 1.5T and 3.0T:

The dS FootAnkle 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the foot and ankle anatomy in adolescent and adult patients that can be interpreted by a trained physician.

dS HiRes Hand/Wrist 16Ch 1.5T and 3.0T:

The dS HiRes Hand/Wrist 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the hand and wrist anatomy in adolescent and adult patients that can be interpreted by a trained physician.

dS Small Extremity 16Ch 1.5T and 3.0T:

The dS Small Extremity 16Ch 1.5T and 3.0T MR Coils are intended to be used in conjunction with Philips 1.5T/3.0T Magnetic Resonance Scanners to produce diagnostic images of the small extremities anatomy in neonate, infant, children, adolescent and adult patients that can be interpreted by a trained physician.

The Indications for Use statements for the subject devices **dS FootAnkle 16Ch 1.5T, dS FootAnkle 16Ch 3.0T, dS HiRes Hand/Wrist 16Ch 1.5T, dS HiRes Hand/Wrist 16Ch 3.0T, dS Small Extremity 16Ch 1.5T and dS Small Extremity 16Ch 3.0T** 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 MR systems,
- Acquisition of MR signals for diagnostic imaging of anatomy (Foot/ankle, Hand/wrist and Small extremities),
- Coil housings and pads designed to allow positioning and stabilization of the anatomy,
- Use of the MR 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 and supplier changes,

- 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, Warnings clarified and updated based on current coil specific risk profile.

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. The verification and validation results demonstrate that the subject devices meet the acceptance criteria and are adequate for their intended use.

Biocompatibility evaluation was conducted for the subject devices in accordance with FDA recognized consensus standards for the biological evaluation of medical devices. The assessment considered the nature and duration of patient contact of the subject devices. Testing included, as appropriate Cytotoxicity, Sensitization and Irritation. The results of the biocompatibility evaluation demonstrated that the materials used in the subject devices are biocompatible for their intended patient contact and duration of use.

Risk management activities were performed to evaluate hazards associated with the design changes. The evaluation demonstrated that identified risks are adequately controlled and that no new risks are introduced, and that the overall residual risks are acceptable.

The non-clinical performance data summarized above demonstrate that the subject devices perform as intended and support a determination of substantially equivalence to the legally marketed predicate devices in terms of safety and effectiveness.

Summary of Clinical Data

Clinical testing was not required to support the determination of substantial equivalence because the indications for use of the subject devices remain similar to those of the predicate devices and the technological differences do not raise different questions of safety or effectiveness.

Conclusion

Based on the 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.