October 18, 2024

Philips Medical Systems Nederland B.V.
Sherry Li
Regulatory Affairs Specialist
Veenpluis 6
5684 PC Best
The Netherlands

Re: K243033
Trade/Device Name: dS Wrist coil 8ch 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: September 22, 2024
Received: September 27, 2024

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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243033

Device Name

dS Wrist coil 8ch 1.5T

Indications for Use *(Describe)*

The dS Wrist Coil 8ch 1.5T is intended to be used in conjunction with Philips 1.5T Magnetic Resonance Scanner to produce diagnostic images of the wrist 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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510(k) Summary

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

Preparation date:	September 23, 2024
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration # 3003768277
Contact person:	Sherry Li, RA Specialist Philips Medical Systems Nederland B.V. Phone: +86 67336660
Trade Name:	**dS Wrist Coil 8ch 1.5T**
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:	8ch Wrist Coil (K222325)
Predicate Classification Name:	Coil, Magnetic Resonance
Predicate Regulation Number:	21 CFR 892.1000
Predicate Device Class:	Class II
Predicate Product Code:	MOS

Device description
The dS Wrist Coil 8ch 1.5T is an 8-channel phased-array coil with rigid volume coils of 8 elements that closely encircle the wrist for high SNR. This coil for Prodiva and MR5300 is a one-piece, hinged design for easy patient set-up. To reduce patient motion artifacts, the dS Wrist coil includes one rigid base plate to fixate the coil & allowing for overhead and at the side examinations.
This coil is only available in 1.5T. This coil is used independently and cannot be combined with any other coils

Indications for use
The dS Wrist Coil 8ch 1.5T is intended to be used in conjunction with Philips 1.5T Magnetic Resonance Scanner to produce diagnostic images of the wrist that can be interpreted by a trained physician.

Fundamental Scientific Technology:
Based on the information provided above, the subject **dS Wrist Coil 8ch 1.5T** is considered substantially equivalent to the primary predicate device 8ch Wrist Coil (K222325) in terms of fundamental design, material and scientific technology. At a high level the **dS Wrist Coil 8ch 1.5T** and the predicate coil are based on the following equivalent elements:

- Similar Indications for use
- Prescription Use Only
- Anatomy of interest is the wrist
- Same magnetic field strength (1.5T)
- Rigid housing design that allows each imaging element to be independently positioned and configured for each patient
- Energy source from the MR scanner

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

- Different compatible MR scanners:
  The subject device is compatible with Philips Prodiva and MR 5300 MR systems, whereas the predicate device is compatible with the GE Signa Prime MR System.
- Different pad materials: Polyscan coating for the predicate device and L&K foil for the subject device.

Clinical and non-clinical testing demonstrates that the safety and effectiveness requirements as outlined in FDA guidance *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*, issued December 11, 2020 were met. No new safety or efficacy concerns are raised as a result of these differences.

Summary of Non- Clinical and Clinical Performance Data:
The subject **dS Wrist Coil 8ch 1.5T** has undergone the following testing in accordance with FDA-recognized consensus standards and as recommended in FDA guidance documents *Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, issued November 18, 2016 and *Magnetic Resonance (MR) Receive-only Coil – Performance Criteria for Safety and Performance Based Pathway*, issued December 11, 2020:

Performance Testing – Non-Clinical:

- **IEC 60601-1** General electrical/mechanical safety
- **IEC 60601-1-2** EMC Immunity, electrostatic discharge testing
- **IEC 60601-2-33** Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- **NEMA-MS-1, 3, 9, 14** Image uniformity and signal-to-noise ratio testing
- **IEC62464-1** International Standard: Magnetic resonance equipment for medical imaging – Part 1: Determination of essential image quality parameters
- **ISO 10993-1** Biological safety evaluation
- **ISO 17664** Cleaning and disinfection validations to support reprocessing instructions

Performance Testing – Clinical:

Acquired Image quality was assessed by U.S. Board Certified radiologist to confirm that images produced on the subject coil have sufficient quality for diagnostic use.

Substantial Equivalence Conclusion:

Substantial equivalence of the **dS Wrist Coil 8ch 1.5T** is demonstrated through the Safety and Performance Based Pathway for magnetic resonance (MR) receive-only coils.

The subject device has similar indications for use and technological characteristics as the predicate device. Substantially equivalent performance is demonstrated by meeting all criterion in the guidance *"Magnetic Resonance (MR) Receive-only Coil –Performance Criteria for Safety and Performance Based Pathway"* issued on December 11, 2020.

The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device according to 807.92(b)(3).