October 3, 2023

Invivo Corporation (Business Trade Name: Philips)
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K232762
Trade/Device Name: dS Breast Coil 7ch 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: September 8, 2023
Received: September 8, 2023

Dear Prithul Bom:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232762

Device Name
dS Breast Coil 7ch 1.5T

Indications for Use *(Describe)*
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 to produce diagnostic images of the breast, chest wall, and axillary tissues 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.

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510(k) Summary (K232762)

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

Preparation date:	August 17, 2023
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration #3003768277
Contact person:	Liselotte Kornmann (primary) Associate Director Regulatory Affairs Philips Medical Systems Nederland B.V. Phone: +31 611621238
Trade Name:	**dS Breast Coil 7ch 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:	Biopsy Breast Coil BBC (K032576 - October 23, 2003)
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 Breast Coil 7ch 1.5T** is a 7-element phased array receive only coil to be used on a 70cm bore Philips 1.5T MR Systems. The coil is designed to work in unison with the Body Coil of the MRI system, which will transmit the radio frequency (RF) signals, so that the coil may receive the resultant RF signal from the excited nuclei. The subject coil is designed to be used in conjunction with Philips Prodiva 1.5T CS and 1.5T CX MR System (K173507) and with Philips MR 5300 System (K212673) with dStream interfaces. The subject coil is designed for optimum coverage and high-resolution visualization of detailed cartilage structures of the breast anatomy. The coil is used independently and cannot be combined with any other coils. The coil is only available in 1.5T version. The open coil housing design of the dS Breast Coil 7ch 1.5T allows for lateral-medial and cranial-caudal access to the breast for both diagnostic breast imaging and interventional exams.

Indications for use
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 to produce diagnostic images of the breast, chest wall, and axillary tissues that can be interpreted by a trained physician.

Fundamental Scientific Technology:
Based on the information provided above, the subject **dS Breast Coil 7ch 1.5T** is considered substantially equivalent to the primary predicate device Biopsy Breast Coil BBC (K032576 - October 23, 2003) in terms of fundamental design, material and scientific technology. At a high level the **dS Breast Coil 7ch 1.5T** and the predicate coil are based on the following equivalent elements:

- Same Indications for use
- Prescription Use Only
- Anatomy of interest is the breast
- 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
- Designed to support access to the breast anatomy for both diagnostic breast imaging and interventional exams

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

- The design of the housing is more simplified than the marketed primary predicate device
- The subject device is compatible with Philips Prodiva and MR 5300 MR systems, whereas the predicate is compatible with the Ingenia family of MR systems.
- There is no 3.0T version of the subject breast coil.

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 Breast Coil 7ch 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 two U.S. Board Certified radiologists to confirm images produced on the subject coil are sufficient quality for diagnostic use.

Substantial Equivalence Conclusion:

Substantial equivalence of the **dS Breast Coil 7ch 1.5T** is demonstrated through the Safety and Performance Based Pathway for magnetic resonance (MR) receive-only coils.

The subject device has the same 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).