October 24, 2023

Philips Medical System Nederlands B.V.
Shruti Sancheti
Regulatory Affairs Manager
Veenpluis 6
Best, Noord-Brabant 5684 PC
Netherlands

Re: K233348
Trade/Device Name: 16 Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: September 29, 2023
Received: September 29, 2023

Dear Shruti Sancheti:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233348

Device Name

16 BREAST COIL

Indications for Use *(Describe)*

The 16 Breast Coil for Canon 1.5T MRI Scanners are designed to provide magnetic resonance images of breast anatomy when used in conjunction with a magnetic resonance scanner. These images are interpreted by a trained physician. When used with a disposable biopsy grid, the device permits access to breast anatomy for biopsy and localization procedures.

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.

510(k) Summary

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

Preparation date:	September 29, 2023
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration # 3003768277
Contact person:	Shruti Sancheti Regulatory Affairs Manager Philips Medical Systems Nederland B.V. Phone: +91 9518546814
Subject Device Trade Name:	**16 Breast Coil**
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 Sentinelle Breast 16ch 1.5T Coil* (K213735)
Classification Name:	Coil, Magnetic Resonance, Specialty
Regulation Number:	21 CFR 892.1000
Review Panel:	Radiology
Device Class:	Class II
Product Code :	MOS

Device description

The **16 Breast Coil** is a receive-only coil to be used with 1.5T Orian and Fortian Canon MR scanners. The coil arrays are designed in a magnetic strength (1.5T) to correspond with the scanner strength.

The **16 Breast Coil** is a phased array design consisting of patient support with three different coil combinations (2, 10 or 16 channels):

1. 16Ch for diagnostic imaging: performed in 16ch combination that consists of two 4ch Lateral coils and the 8ch Medial array coil.
2. 10ch for bilateral interventional procedures requiring lateral access: performed in 10ch configuration that consists of the 8ch Medial array coil and two 1ch Loop coils (right and left).
3. 2ch for unilateral interventional procedures allowing both lateral and medial access: performed in 2ch configuration that consists of two 1ch Loop coils (right and left) and medial plug.

The coils receive magnetic resonance signals generated in hydrogen nuclei (protons) in the Breast while blocking the high-frequency magnetic field applied by the MRI scanner at specified timings.

Images are typically generated as axial, sagittal, coronal and oblique slices and include full coverage of the breast anatomy.

The **16 Breast Coil** is tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

The Variable Coil Geometry design of the **16 Breast Coil** allows each imaging element to be independently positioned and configured for each patient. Patients can then be positioned quickly and effectively as the imaging elements can be positioned as close to the breast as possible optimizing the signal-to-noise ratio for each individual patient. For clinical imaging, coil housings are placed next to the tissue to help minimize motion artifacts due to patient motion during scanning.

The subject **16 Breast Coil** also includes a tabletop compression system which facilitates immobilization of the breast for imaging and interventional procedures and serves to hold the individual imaging coils in proximity to the breast(s). The intent of this is to reduce motion artifacts and ensure the imaging elements are positioned as close to the breast(s) as possible to optimize signal-to-noise ratio and image quality.

Indications for use

The **16 Breast Coil** for Canon 1.5T MRI Scanners are designed to provide magnetic resonance images of breast anatomy when used in conjunction with a magnetic resonance scanner. These images are interpreted by a trained physician. When used with a disposable biopsy grid, the device permits access to breast anatomy for biopsy and localization procedures.

Both the subject and predicate devices are 16 channel coils and intended to be used in conjunction with a 1.5T Magnetic Resonance Scanner(s) to produce diagnostic images of the breast anatomy that can be interpreted by a trained physician. When used with a disposable biopsy grid, the device permits access to breast anatomy for biopsy and localization procedures. The indications for use of the new device falls within the intended use of the predicate device and, therefore, the two devices have the same intended use.

The minor modifications in the indications for use statement for the subject **16 Breast Coil** in comparison to *dS Sentinelle Breast 16ch 1.5T Coil* are as below:
a) New device trade name, b) Compatibility with 1.5T Orian and Fortian Canon MR scanners.

Fundamental Scientific Technology:
Based on the information provided above, the subject **16 Breast Coil** is considered substantially equivalent to the primary predicate device dS Sentinelle Breast 16ch 1.5T Coil (K213735) in terms of fundamental design, materials and scientific technology. At a high level, the **16 Breast Coil** and the predicate coil are based on the following equivalent elements:

- Principle of operation,
- Prescription Use Only,
- Anatomy of interest is the breast,
- Same magnetic field strength (1.5T),
- 2/10/16-Channel combinations, receive only phased-array coil with decoupling methodology,
- Rigid housing design that allows each imaging element to be independently positioned and configured for each patient,
- Compression plates supported by the device are used to immobilize the breast tissue,
- Patient support to allow for three different imaging combinations,
- 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 devices:

- The subject device is compatible with 1.5T Orian and Fortian Canon MR scanners, whereas the predicate device is compatible with the 70 cm bore Philips Ingenia 1.5T MR system; different system interface connector and geometry for Canon MR scanners' tabletop;
- Different fabrics used for support pads in subject and predicate devices.

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 **16 Breast Coil** 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 60601-1-6** General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 60601-1-2** EMC - Immunity, electrostatic discharge
- **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** Image signal-to-noise (SNR) and Image uniformity
- **NEMA MS 14** Surface heating
- **ISO 10993-1** Biological safety evaluation
- **ISO 17664-2** Cleaning and disinfection validations to support reprocessing instructions

Performance Testing – Clinical:

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

Substantial Equivalence Conclusion:

Substantial equivalence of the **16 Breast Coil** is demonstrated through the Safety and Performance Based Pathway for magnetic resonance (MR) receive-only coils.

The subject device has substantially equivalent 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).