August 8, 2022

Invivo Corporation (Business Trade Name: Philips)
% Jennifer Conyac
Regulatory Affairs Specialist
3545 SW 47th Avenue
GAINESVILLE FL 32608

Re: K213727
Trade/Device Name: dS Sentinelle Breast 16ch 3.0T Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: July 1, 2022
Received: July 5, 2022

Dear Jennifer Conyac:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Michael D. O'Hara, Ph.D.
Deputy 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)*
K213727

Device Name
dS Sentinelle Breast 16ch 3.0T Coil

Indications for Use *(Describe)*
The dS Sentinelle Breast 16ch 3T Coil are intended to be used in conjunction with Philips 3.0T Magnetic Resonance Scanners 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.

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
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHILIPS

510(k) Summary

K213727

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

510(k) Owner:	Invivo Corporation (Business Trade Name: Philips) 3545 SW 47th Ave Gainesville, FL 32608 Establishment Registration #1056069	
Contact:	Jennifer Conyac Regulatory Affairs Manager Phone: 1 (352) 384-8629 E-mail: jennifer.bonacci@philips.com	
Preparation Date:	November 23, 2021	
Name of Device:	**dS Sentinelle Breast 16Ch 3.0T Coil**	
Classification:	Classification Name:	Coil, Magnetic Resonance, Specialty
	Classification Regulation:	21 CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Product code:	MOS
Primary Predicate Device:	Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5T/3T MRI Systems (K112112 – cleared August 25, 2011)	
Device Description:	The **dS Sentinelle Breast 16 Ch 3.0T MR Coils** is a receive only coil to be used on a 70cm bore Philips Ingenia 3.0T MR System. The coil arrays are designed to correspond with the scanner strength. The **dS Sentinelle Breast 16Ch 3T coil** is a phased array design consisting of patient support with three different coil configurations (2, 10 or 16 channels): 1. 16Ch for diagnostic imaging: performed in 16Ch configuration that consists of two dS Sentinelle Lateral 4Ch coils and the dS Sentinelle Medial 8Ch coil. 2. 10Ch for bilateral interventional procedures requiring lateral access: performed in 10Ch configuration that consists of the dS Sentinelle Medical 8Ch coil and two dS Sentinelle Lateral 1Ch coils (right and left). 3. 2Ch for unilateral interventional procedures allowing both lateral and medial access: performed in 2Ch configuration that consists of two dS Sentinelle Lateral 1Ch coils (right and left).	

PHILIPS

	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. The coil arrays include 4Ch right and left lateral coils, a medial coil and 1Ch right and left lateral biopsy coils. Images are typically generated as axial, sagittal, coronal and oblique slices and include full coverage of the breast anatomy. The **dS Sentinelle Breast 16Ch 3T Coil** is tuned to receive RF frequency corresponding to the proton precession in a 3.0 tesla magnetic field (respectively), which is governed by the Larmor equation. The Variable Coil Geometry design of the **dS Sentinelle Breast 16Ch 3T 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 dS Sentinelle Breast Coil system 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 **dS Sentinelle Breast 16ch 3T Coil** are intended to be used in conjunction with Philips 3.0T Magnetic Resonance Scanners 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.
Fundamental Scientific Technology:	Based on the information provided above, the subject **dS Sentinelle Breast 16Ch 3.0T Coils** are considered substantially equivalent to the primary currently marketed and predicate device Sentinelle Breast MRI Tabletop with 16 Channel Coil Array for Siemens 1.5T/3T MRI Systems (K112112 – cleared August 25, 2011) in terms of fundamental design, material and scientific technology. At a high level the **dS Sentinelle Breast 16Ch 3T Coil** and the predicate coil are based on the following equivalent elements: • The same Indications for Use • Prescription Use Only • Anatomy of interest is the breast • Same magnetic field strength (3.0T) • 2/10/16-Channel configurations, receive only phased-array coil with decoupling methodology

PHILIPS

	• 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 configurations • Energy source from the MR scanner • Design features to support access to the breast anatomy for interventional biopsy procedures The following technological differences exist between the subject and predicate device: • Compatible with different MR Scanners (Philips vs. Siemens); different cable/connector and geometry for Philips' MR scanner tabletop • The exterior housing of the subject coil is of materials that were modified for Philips Branding purposes • The biopsy grid plate of the subject coil is provided clean, single-use but non-sterile 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 Sentinelle Breast 16Ch 3.0T 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: <u>Performance Testing – Non-Clinical:</u> - **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 testing - **IEC 60601-2-33** Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis - **NEMA-MS-1,3,6,9** 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 <u>Performance Testing – Clinical:</u>

PHILIPS

	• Acquired Image quality was assessed by a U.S. Board Certified radiologist to confirm images produced on the subject coils are sufficient quality for diagnostic use.
Substantial Equivalence Conclusion:	Substantial equivalence of the **dS Sentinelle Breast 16 Ch 3.0T Coil** 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.