December 23, 2021

Invivo Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K213766
Trade/Device Name: dS FootAnkle 16Ch Coils for 1.5T and 3.0T, dS HiRes HandWrist 16Ch Coils for 1.5T and 3.0T, ds Small Extremity 16Ch Coils for 1.5T and 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: November 30, 2021
Received: December 1, 2021

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 (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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213766

Device Name
dS FootAnkle 16ch 1.5T and 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 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K21xxxx

Device Name
dS HiRes Hand/Wrist 16ch 1.5T and 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K21xxxx

Device Name
dS Small Extremity 16ch 1.5T and 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 on adult and pediatric 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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PHILIPS

K213766

510(k) Summary

Philips *Orthopedic MR Coils:*

dS FootAnkle, dS HiRes HandWrist, dS Small Extremity 16Ch Coils for 1.5T and 3.0T

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:	Ann Lebar Head of Regulatory Phone: 1 (414) 217-6244 E-mail: ann.lebar@philips.com	
Preparation Date:	October 29, 2021	
Name of Device:	***Philips Orthopedic MR Coils:*** ***dS FootAnkle 16Ch Coils for 1.5T and 3.0T*** ***dS HiRes HandWrist 16Ch Coils for 1.5T and 3.0T*** ***dS Small Extremity 16Ch Coils for 1.5T and 3.0T***	
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 Devices:	dS FootAnkle 16Ch Coil for 1.5T, Invivo Corporation, K162177 cleared on 09/14/2016 Hand-Wrist Coil 16Ch Coil for 1.5T, Invivo Corporation, K103149 cleared on 01/03/2010 dS Small Extremity 16Ch 1.5T Coil, Invivo Corporation, K162863 cleared on 11/7/2016	

PHILIPS

510(k) Summary
Philips *Orthopedic MR Coils:*
dS FootAnkle, dS HiRes HandWrist, dS Small Extremity 16Ch Coils for 1.5T and 3.0T
prepared in accordance with 21 CFR §807.92.

Device Description:	The Philips ***Orthopedic MR Coils*** are designed for use with Magnetic Resonance Imaging (MRI) systems. The coils are 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 devices have 16-elements and are for use with Philips Ingenia 1.5T and 3.0T MR Systems with dStream interface (K193215). The devices are designed for optimum coverage and high-resolution visualization of detailed cartilage structures of the body anatomy (foot/ankle, hand/wrist, small extremity). The coil is used independently and cannot be combined with any other coils. The coils are available in both 1.5T and 3.0T magnetic strengths.
Indications for Use:	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 that can be interpreted by a trained physician. 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 that can be interpreted by a trained physician. 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 on adult and pediatric patients that can be interpreted by a trained physician.
Fundamental Scientific Technology:	The subject Philips ***Orthopedic MR Coils*** are considered substantially equivalent to the primary currently marketed predicate devices (dS FootAnkle 16Ch Coil for 1.5T, Invivo Corporation, K162177 cleared on 09/14/2016; Hand-Wrist Coil 16Ch Coil for 1.5T, Invivo Corporation, K103149 cleared on 01/03/2010; and dS Small Extremity 16Ch 1.5T Coil, Invivo Corporation, K162863 cleared on 11/7/2016) in terms of fundamental scientific technology. The subject coils are similar in design, material, chemical composition and energy source to the legally marketed predicate devices.

	At a high level, the subject coils as part of this submission and the predicate devices are based on the following same technological elements: • Prescription use • Coil designs are receive-only phased array coils • Decoupling methodology • Patient contacting materials and chemical composition are known materials that have been assessed for compliance with recognized biocompatibility standards • Energy source for the coils is the MRI scanner • No energy is supplied by the coils • Coils designs are targeted for imaging the anatomy of interest • Mechanical designs are contoured for the patient anatomy The following technological differences exist between the subject and predicate devices: • Coil geometry housing design: Housing with similar design. Subject housing design is slightly different design to more closely mimic subject patient anatomy and provide additional patient comfort. • System compatibility: New coil compatible with 3.0T MR scanner. The intended use for subject coils is the same as for the predicate device, specifically the coils are intended to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images that can be interpreted by a trained physician; only differing in name of the coil and the reference to the specific body part (e.g., foot and ankle vs anatomy of interest). For the ***dS Small Extremity 16Ch Coils for 1.5T and 3.0T,*** it was also determined that the coils can be used to assess both adult and pediatric patients which has been added to the indications for use. 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.
Summary of Non-Clinical and Clinical	The Philips ***Orthopedic MR Coils*** have undergone the following testing in accordance with FDA-recognized consensus standards and as recommended in FDA guidance documents *Submission of*

PHILIPS

510(k) Summary
Philips *Orthopedic MR Coils:*
dS FootAnkle, dS HiRes HandWrist, dS Small Extremity 16Ch Coils for 1.5T and 3.0T
prepared in accordance with 21 CFR §807.92.

Performance Data:	*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:* • Image Signal to Noise and Image Uniformity characterization (NEMA MS 1, 3, 9 and IEC 62464-1) • Surface heating (ANSI/AAMI ES 60601-1 and NEMA MS 14) • Acquired Image quality was assessed by a U.S. Board Certified radiologist to confirm images produced on the subject coil are sufficient quality for diagnostic use. • Presence of decoupling mechanisms • EMC – Immunity, electrostatic discharge (IEC 60601-1-2) • General electrical/mechanical safety (IEC 60601-2-33 and AAMI/ANSI ES 60601-1) • Biocompatibility evaluation (ISO 10993 series) The performance testing demonstrated that the Philips Orthopedic MR Coils are safe and effective for the intended use(s) and will perform in a manner that demonstrates substantial equivalence to the predicate devices and meets predefined performance criteria.

PHILIPS

510(k) Summary

Philips *Orthopedic MR Coils:*

dS FootAnkle, dS HiRes HandWrist, dS Small Extremity 16Ch Coils for 1.5T and 3.0T

prepared in accordance with 21 CFR §807.92.

Substantial Equivalence Conclusion:	The Philips ***Orthopedic MR Coils (dS FootAnkle 16Ch Coils for 1.5T and 3.0T, dS HiRes HandWrist 16Ch Coils for 1.5T and 3.0T, and dS Small Extremity 16Ch Coils for 1.5T and 3.0T***) are substantially equivalent to the predicate devices (dS FootAnkle 16Ch Coil for 1.5T, Invivo Corporation, K162177 cleared on 09/14/2016; Hand-Wrist Coil 16Ch Coil for 1.5T, Invivo Corporation, K103149 cleared on 01/03/2010; and dS Small Extremity 16Ch 1.5T Coil, Invivo Corporation, K162863 cleared on 11/7/2016) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical and clinical performance tests, which complied with the requirements specified in FDA-recognized consensus standards and guidance documents. The results of these tests demonstrate that ***Philips Orthopedic MR Coils (dS FootAnkle 16Ch Coils for 1.5T and 3.0T, dS HiRes HandWrist 16Ch Coils for 1.5T and 3.0T, and dS Small Extremity 16Ch Coils for 1.5T and 3.0T***) meet the acceptance criteria and are adequate for this intended use.