October 29, 2021

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: K213351
Trade/Device Name: ds Head 32ch 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: October 7, 2021
Received: October 8, 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)*
K213351

Device Name
dS Head 32ch 3.0T

Indications for Use *(Describe)*
The dS Head 32ch 3.0T MR Coil is intended to be used in conjunction with a Philips 3.0T Magnetic Resonance Scanner to produce diagnostic images of the head 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)

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 K213351 K213351

prepared in accordance with 21 CFR §807.92

Date Prepared:	October 26, 2021	
Manufacturer:	Invivo Corporation (Business Trade Name: Philips) 3545 SW 47th Ave Gainesville, FL 32608 Establishment Registration #1056069	
Primary Contact Person: **Secondary Contact Person:**	Sarah Pleaugh Regulatory Affairs Specialist sarah.pleaugh@philips.com Ann Lebar Head of Regulatory Affairs ann.lebar@philips.com	
Device Name:	dS Head 32ch 3.0T	
Classification:	Classification Name:	Coil, Magnetic Resonance, Specialty
	Classification Regulation:	21 CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	MOS
Primary Predicate Device:	Trade name:	Models HRB-127-32 High Resolution Brain Coil
	Manufacturer:	Invivo Corporation
	510(k) Clearance:	K082916
	Classification Name:	Coil, Magnetic Resonance, Specialty
	Classification Regulation:	21 CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	MOS
Reference Device:	Trade name:	Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems
	Manufacturer:	Philips Medical Systems Nederland B.V.

PHILIPS

	510(k) Clearance:	K110151/K193215
	Classification Name:	Magnetic Resonance Diagnostic Device
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Codes:	LNH, LNI, MOS
Device Description:	The subject dS Head 32ch 3.0T Coil is a receive-only, phased-array radiofrequency (RF) coil designed for high-resolution head examinations on adult and pediatric patients. The coil is intended for use with Philips magnetic resonance (MR) scanners with a 3.0 tesla magnetic field strength.	
Indications for Use:	The dS Head 32ch 3.0T MR Coil is intended to be used in conjunction with a Philips 3.0T Magnetic Resonance Scanner to produce diagnostic images of the head on adult and pediatric patients that can be interpreted by a trained physician.	
Fundamental Scientific Technology:	The subject dS Head 32ch 3.0T MR Coil is similar in design, material, and energy source to the legally marketed predicate device, Models HRB-127-32 High Resolution Brain Coil (K082916). The subject and predicate devices are based on the following same technological elements: · Prescription use · Coil designs are 32-channel, receive-only, phased array RF coils · Compatible field strength (3.0T) · Decoupling methodology · Patient contacting materials are known materials that have been assessed for compliance with recognized biocompatibility standards · Energy source for the coils is the MRI scanner · Coils designed for imaging the head anatomy · Coil mechanical design is a split housing to facilitate patient positioning · Manufactured for use with Philips MRI scanners The following technological differences exist between the subject and predicate devices: · Predicate device is an analog coil whereas the subject dS Head 32ch 3.0T MR coil is a digital coil.	

PHILIPS

	· Different system cable connectors to interface with the digital MRI scanners. These differences in technology are supported by the MR system and digital coil designs cleared in the reference device Philips Ingenia MR Systems (K110151/K193215), as well as the safety and performance testing provided in this submission. The subject coil performs as intended and does not raise new issues of safety or effectiveness.
Summary of Non-Clinical and Clinical Performance Data:	The subject dS Head 32ch 3.0T Coil met all safety and performance criteria outlined in the FDA guidance "*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 on both adult and pediatric patient populations - 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)
Substantial Equivalence Conclusion:	Substantial equivalence of the dS Head 32ch 3.0T MR 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 and reference devices. 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.