August 31, 2022

Invivo Corporation (Business Trade Name: Philips)
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K222325
Trade/Device Name: 8ch Wrist Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: August 1, 2021
Received: August 2, 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT 8C: 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)*
K222325

Device Name
8ch Wrist Coil

Indications for Use *(Describe)*
The 8ch Wrist Coil is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance scanner to produce diagnostic images of the 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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 Specialist Phone: +1 (352) 384-8629 E-mail: jennifer.bonacci@philips.com	
Preparation Date:	July 27, 2022	
Name of Device:	**8ch Wrist 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 Trade Name:	MRI Devices Corporation *Models HRW-63-8 and HRW-127-8 Wrist Array Coils (K050622 – cleared 08April2005)*	
Primary Predicate Classification:	Classification Name: Coil, Magnetic Resonance, Specialty Classification Regulation: 21 CFR 892.1000 Classification Panel: Radiology Device Class: Class II Product code: MOS	

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Device Description:	The **8ch Wrist Coil** magnetic resonance (MR) coil is a receive only phased array coil with 8 channels for wrist imaging. This Wrist Coil is designed for use with the SIGNA Prime (K211980). The **8ch Wrist Coil** is designed to be used vertically at the patient's sideor horizontally overhead. The wrist array comes with two rigid base plates (for flat or curved tabletops) for fixation to reduce patient motion. The coil receives magnetic resonance signals generated in hydrogen nuclei(protons) in the wrist while blocking the high-frequency B1 field applied bythe MRI scanner at specified timing. The **8ch Wrist 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. Images are typically generated as axial, sagittal, coronal oblique slices and include coverage of the wrist anatomy.

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Indications for Use:	The 8ch Wrist Coil is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance Scanner to produce diagnostic images of the wrist anatomy that can be interpreted by a trained physician.
Fundamental Scientific Technology:	Both the subject and predicate devices have the same indications for use and fundamental design and scientific technology: • Prescription use • Anatomy of interest is the wrist • 8-channel, receive only phased-array coil with decoupling methodology • Designed for use with the same MRI scanner manufacturer (GE) and magnetic strength (1.5T) • Rigid housing design (anterior and posterior coil parts) that are opened and closed to facilitate wrist examinations • Connected to the MR system with cable/connectors • Energy source is the same • Patient contacting materials have been assessed for compliance with biocompatibility standards • Non-sterile and reusable • Cleaned and disinfected by the user prior to use Compared to the predicate (K050622), the main difference is that the subject coil is designed for compatibility with the SIGNA Prime (K211980). Therefore, the cable/connector design is different than the predicate K050622 wrist coils, which were cleared for use with the GE 1.5T Signa Excite I, II, and III MRI systems. Based on the non-clinical performance testing and clinical images reviewed by a radiologist provided in this submission, this difference in technology does not raise new issues of safety or effectiveness. The subject coil, when connected to the compatible MR scanner, performs the intended use with no user or patient risks identified.
Summary of Non-Clinical and Clinical Performance Data:	The **8ch Wrist 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> • NEMA MS-1, NEMA MS-9, IEC 62464-1 - *Image Signal to Noise (SNR)* • NEMA MS-3 - *Image uniformity* • NEMA MS 14 - *Surface heating* • *Decoupling circuit* • IEC 60601-1-2 - *EMC Immunity, electrostatic discharge testing* • IEC 60601-2-33, AAMI/ANSI ES 60601-1 - *General electrical/mechanical safety*

	• ISO 10993-1 Biological safety evaluation • ISO 17664 Cleaning and disinfection validations to support reprocessing instructions <u>Performance Testing – Clinical:</u> • US Board Certified radiologist's review of clinical images The performance testing demonstrated that the **8ch Wrist Coil** are safe and effective for the intended use(s), meets predefined performancecriteria and will perform in a manner that demonstrates substantial equivalence to the predicate device (K050622, 04/08/2005).
Substantial Equivalence Conclusion:	The **8ch Wrist Coil** is substantially equivalent to the primary currently marketed and predicate device (K050622, 04/08/2005) in terms of design features, fundamental scientific technology, indicationsfor 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 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).