August 23, 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: K222257
Trade/Device Name: 1.5 T/R Quad Extremity Coil, 1.5T 8CH T/R Knee Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: July 26, 2022
Received: July 27, 2022

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)*
K222257

Device Name
1.5T T/R Quad Extremity Coil and 1.5T 8CH T/R Knee Coil

Indications for Use *(Describe)*
The 1.5T T/R Quad Extremity Coil is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance Scanner to produce diagnostic images of the lower extremities that can be interpreted by a trained physician.

The 1.5T 8CH T/R Knee Coil is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance Scanner to produce diagnostic images of the knee 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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PHILIPS

K222257

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 Bonacci Regulatory Affairs Specialist Phone: +1-352-384-8629 **E-mail:** jennifer.bonacci@philips.com
Preparation Date:	July 25, 2022
Name of Device(s):	**1.5T T/R Quad Extremity Coil** **1.5T 8CH T/R Knee Coil**
Device Classification:	Classification Name – Coil, Magnetic Resonance, Specialty Classification Regulation – 21 CFR 892.1000 Classification Panel – Radiology Device Class – Class II Product Code – MOS
Predicate Device:	**Quadrature Lower Extremity Coil**, K934396, cleared November 24, 1993
Predicate Device Classification:	Classification Name – Coil, Magnetic Resonance, Specialty Classification Regulation – 21 CFR 892.1000 Classification Panel – Radiology Device Class – Class II Product Code – MOS
Predicate Device:	**HRK-63-8 Knee Array Coil**, K032633, cleared September 25, 2003
Predicate Device Classification:	Classification Name – Coil, Magnetic Resonance, Specialty Classification Regulation – 21 CFR 892.1000 Classification Panel – Radiology Device Class – Class II Product Code – MOS
Device Description:	The **1.5T T/R Quad Extremity Coil** is quadrature Transmit and Receive coils. At 1.5T the coil can be used in 3 different operational modes: QuadKnee, QuadFoot and QuadAnkle. The coil is designed to image the Knee, Foot and Ankle, but can also be used for other parts of the lower extremities.

The base of the coil is attached to a base plate and can be moved to scan either the Left or Right extremity. The coil is moved into position (Left to Right) and locked into place, the patient is then positioned in the base, the top section of the coil is placed over the patient and the latched closed. The fixed position of the coil and helps prevent the patient form moving, reducing artifact.

This coil is used independently and can't be combined with any other coils.

The **1.5T T/R Quad Extremity Coil** is compatible with SIGNA Prime MRI Systems with P-Port Connector. It consists of a birdcage quadrature coil. During transmit phase, the coil is resonated by the RF power source of MR system, to excite hydrogen nuclei (protons) in the anatomy. The quadrature coil detects the magnetic resonance signals generated by hydrogen nuclei (protons) in the knee during the receive phase.

The coil is tuned to transmit and receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

The **1.5T 8CH T/R Knee Coil** is an 8 element phase array coil with a T/R quadrature birdcage shell, designed to image the knee. The base of the coil is attached to a base plate and can be moved to scan either the Left or Right Knee. The patient is positioned in the base, the top section of the coil is placed over the patient and the latched closed, which locks the position of the coil and helps prevent the patient form moving, reducing artifact.

The transmit shell consist of a twist birdcage quadrature coil, resonated by the RF power source of MR system, to excite hydrogen nuclei (protons) in the anatomy.

The coil receivers consist of 8 phased array elements that detect the magnetic resonance signals generated by hydrogen nuclei (protons) in the knee while blocking the high-frequency B1 field applied by the coil transmit shell at specified timings.

The coil is tuned to transmit and receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

This coil is used independently and cannot be combined with any other coils.

The **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** are compatible with SIGNA Prime MRI systems with a P-Port connector.

Indications for Use: The **1.5T T/R Quad Extremity Coil** is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance Scanner to produce diagnostic

images of the lower extremities that can be interpreted by a trained physician.

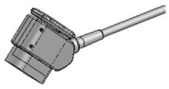
The **1.5T 8CH T/R Knee Coil** is intended to be used in conjunction with a SIGNA Prime Magnetic Resonance Scanner to produce diagnostic images of the knee that can be interpreted by a trained physician.

Fundamental Scientific Technology:

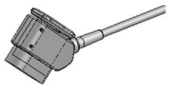
The subject 1.5T T/R Quad Extremity Coil and 1.5T 8CH T/R Knee Coil are similar in design, material, chemical composition and energy source to the legally marketed and predicate devices (Quadrature Lower Extremity Coil: K934396, November 24, 1993; and HRK-63-8 Knee Array Coil: K032633, September 25, 2003). At a high level, the **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** and the predicate devices are based on the following same characteristics:

- Clinical
- Technical
- Biological

The detailed comparisons are:

Item	Quadrature Lower Extremity Coil (Predicate Device, K934396)	1.5T T/R Quad Extremity Coil (Subject Device)
Cable assembly / system connector		
Intended Use population	Adult	The target population for the devices are any patient scheduled for MRI exam of the knee, lower limb and extremities.
Clinical application site	Musculoskeletal structures, soft tissue and vascular structure of the lower extremities	Knee / Foot / Lower Extremity
Type of device contact to body	Body surface	Body surface
Indications for Use	Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the musculoskeletal structures, soft tissue and vascular structures of the lower extremities.	The **1.5T T/R Quad Extremity Coil** is intended to be used in conjunction with a GE 1.5T Magnetic Resonance Scanner to produce diagnostic images of the lower extremities that can be interpreted by a trained physician.
Illness stage and degree for use	Across all stages and degree of illness	Across all stages and degree of illness
Operating Environment	Hospital MRIs across all departments; imaging	Hospital MRIs across all departments; imaging

	centers; specialty offices; primary and secondary care centers	centers, specialty offices, primary and secondary care centers
Frequency range	63.86 MHz	63.86 MHz
Coil Design	Quadrature transmit-receive coil	Quadrature transmit-receive coil
Magnetic Field Orientation (B0)	Horizontal	Horizontal
Decoupling method	System body coil does not transmit when this device is connected, no decoupling necessary	System body coil does not transmit when this device is connected, no decoupling necessary
Number of Channels / Preamplifiers	Quadrature combined single channel	Quadrature combined single channel (QLE)
Housing Material	Hylex P1010FR and Lexan 925 polycarbonate	Hylex P1010FR and Lexan 925 polycarbonate
Base Pad	Polyether foam with vinyl-based spray-on coating	Polyether foam with vinyl-based spray-on coating
System Connector / Compatibility	GE legacy "A-Port" connector	GE "P-Port connector
Patient Contact materials	- Hylex P1010FR and Lexan 925 polycarbonate - Polyether foam with vinyl-based spray-on coating	- Hylex P1010FR and Lexan 925 polycarbonate - Polyether foam with vinyl-based spray-on coating
Components	No incorporation of any medicinal substances.	No incorporation of any medicinal substances.

Item	**HRK-63-8 Knee Array Coil (Predicate Device, K032633)**	**1.5T 8CH T/R Knee Coil (Subject Device)**
Cable assembly / system connector		
Intended Use population	Adult	The target population for the devices are any patient scheduled for MRI exam of the knee, lower limb and extremities.
Clinical application site	Knee	Knee
Type of device contact to body	Body surface	Body surface
Indications for Use	To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the knee that can be	The **1.5T 8CH T/R Knee Coil** is intended to be used in conjunction with a GE 1.5T Magnetic Resonance Scanner to produce diagnostic images of the knee that

	interpreted by a trained physician.	can be interpreted by a trained physician.
Illness stage and degree for use	Across all stages and degree of illness	Across all stages and degree of illness
Operating environment	Hospital MRIs across all departments; imaging centers; specialty offices, primary and secondary care centers	Hospital MRI s across all departments; imaging centers, specialty offices, primary and secondary care centers
Frequency range	63.86 MHz	63.86 MHz
Coil Design	Volume phased-array, transmit-receive coil	Volume phased-array, transmit-receive coil
Magnetic Field Orientation (B0)	Horizontal	Horizontal
Decoupling method	System body coil does not transmit when this device is connected, no decoupling necessary	System body coil does not transmit when this device is connected, no decoupling necessary
Number of Channels / Preamplifiers	8 channels / preamplifiers	8 channels / preamplifiers
Housing Material	Lexan 925 polycarbonate	Lexan 925 polycarbonate
Base Pad	Polyether foam with vinyl-based spray-on coating	Polyether foam with vinyl-based spray-on coating
System Connector / Compatibility	GE legacy "A-Port" connector	GE "P-Port" connector
Patient contact materials	- Lexan 925 polycarbonate - Polyether foam with vinyl-based spray-on coating	- Lexan 925 polycarbonate - Polyether foam with vinyl-based spray-on coating
Components	No incorporation of any medicinal substances.	No incorporation of any medicinal substances.

Based on the information provided above, the difference between **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil**, and predicate devices, is the connector design, as the predicate device connects to legacy GE Signa 1.5T system. **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** connects to SIGNA Prime (K211980). The subject devices are considered substantially equivalent to the primary currently marketed and predicate device (Quadrature Lower Extremity Coil: K934396, November 24, 1993; and HRK-63-8 Knee Array Coil: K032633, September 25, 2003) in terms of fundamental scientific technology.

Summary of Non-Clinical and Clinical Performance Data:

The 1.5T T/R Quad Extremity Coil and 1.5T 8CH T/R Knee 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.

<u>Performance Testing – Non-Clinical:</u>

- ANSI/AAMI ES 60601-1 and NEMA MS 14 Surface heating
- IEC 60601-1-2 EMC Immunity, electrostatic discharge testing

- IEC 60601-2-33, AAMI/ANSI ES 60601-1 General electrical/mechanical safety
- NEMA MS-1, NEMA MS-3, NEMA MS-9 and IEC 62464-1 Image Signal to Noise and Image Uniformity characterization
- IEC 60601-2-33 and NEMA MS-8 Specific Absorption Rate
- ISO 10993-1 Biological safety evaluation
- ISO 17664 Cleaning and disinfection validations to support reprocessing instructions

Performance Testing – Clinical:

- per NEMA PS 3.1 - 3.20, Sample clinical images for the target anatomical locations were provided in DICOM format to demonstrate the images produced are of sufficient quality for diagnostic use. (Section 20 of 510k Submission)
- There was no adverse event reported during clinical performance testing.
- The clinical performance testing plan and report is provided with a statement from a US Board Certified radiologist that can support the ability of the device to generate diagnostic quality images. (Section 20 of 510k Submission)

The performance testing demonstrated that the **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** are safe and effective for the intended use(s) and meets predefined performance criteria.

Substantial Equivalence Conclusion:

The **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** are substantially equivalent to the primary currently marketed and predicate device (Quadrature Lower Extremity Coil: K934396, November 24, 1993; and HRK- 63-8 Knee Array Coil: K032633, September 25, 2003) in terms of indications for use, design characteristics, fundamental scientific technology, materials, sterilization, shelf life, 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 **1.5T T/R Quad Extremity Coil** and **1.5T 8CH T/R Knee Coil** met the acceptance criteria and is adequate for this intended use.