DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 14, 2016

Invivo Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th street, NW
BUFFALO MN 55313

Re: K162177
Trade/Device Name: dS FootAnkle 16ch 1.5T Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: August 31, 2016
Received: September 1, 2016

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162177

Device Name
dS FootAnkle 16ch 1.5T Coil

Indications for Use *(Describe)*
The dS FootAnkle 16ch 1.5T Coil is intended to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the foot and ankle 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

Submitted by:	Invivo Corporation 3545 SW 47th Ave Gainesville, FL 32608
Establishment Name	Invivo Corporation
Establishment Registration Number:	1056069
Contact Person:	Ken Revennaugh Title: Director of Quality and Regulatory Invivo Corporation 3545 SW 47th Ave Gainesville, FL 32608 Phone: (352) 384-8590 E-mail: ken.revennaugh@philips.com
Date Prepared:	August 30, 2016
Trade Name:	dS FootAnkle 16ch 1.5T Coil
Common Name:	Magnetic resonance diagnostic device
Classification Name:	Coil, Magnetic Resonance, Specialty
Classification Regulation Number:	892.1000
Classification:	Class II
Classification Panel:	Radiology
Product code:	MOS

Device Description:

The proposed dS FootAnkle 16ch 1.5T Coil is designed for use with Magnetic Resonance Imaging (MRI) systems. The coil is 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 proposed dS FootAnkle 16ch 1.5T Coil is a volume phased array receive-only coil for high resolution diagnostic imaging of foot and ankle with coil housing dimensions to be 14.46x8.13x12.65 inches. The coil is constructed on molded polycarbonate (Lexan 925) former using Kapton rigid-Flex PCB (loop elements) and FR-4 PCB (feedboard, interface boards) and urethane-jacketed cable to connect to MR system. The coils provide unilateral images (Left and Right) of the anatomy of interest. The coil is designed for high resolution diagnostic imaging of the foot and ankle anatomical regions.

The coil pads are made of Urethane foam with Polyscan coating with one of the Base Plate Pad to comfort other foot (not being imaged) have PolyDry Healthcare Fabric Exterior.

Variations between the proposed dS FootAnkle 16ch 1.5T Coil and currently marketed and predicate device FAC-63 Foot and Ankle Coil include MR system compatibility and a 16-channel connection to the MRI system. Mechanical design changes include modifications to the connector to permit the 16-channel connection and the specified MR system compatibility. In addition, modifications to the overall dimensions improve workflow as well as meet customer requirements.

<u>Proposed changes to the device</u>

- Coil housing material changed from Lexan 950 to Lexan 925 for ease of availability with no impact to device safety and effectiveness
- Coil pad coating changed from Guardian MPGX to Polyscan coating for ease of availability with no impact to device safety or effectiveness.
- Channel count was increased from 8 channels to 16 channels to meet the customer/market needs with no impact on device to safety and effectiveness.
- The overall coil dimensions were changed from 12.75” x 7.04” x 11.23” to 14.46” x 8.13” x 12.65” to accommodate more channels with no impact to device safety and effectiveness.

The proposed Model dS FootAnkle 16ch 1.5T Coil will operate with the Philips 1.5T MRI Scanners with dStream capabilities. The proposed Model dS FootAnkle 16ch 1.5T Coil is a 16-channel receive-only coil.

Photograph:

Patient Safety

Description of design that assures that the coil will remain decoupled:

Each coil incorporates a redundant decoupling strategy. A fast recovery back-to-back PIN diode pair is placed in series with an inductor across a capacitor. The inductor is tuned to shift the resonant frequency of the coil. There is also a fuse in series with the loop that would break loop resonance in event of high currents. During system transmit pulses, a DC voltage is supplied to each of the 16 channels of the array by the MRI system. This voltage drives the PIN diodes so they conduct, thus engaging the decoupling circuit. The coil resonant frequency then shifts away from the system resonant frequency. The coil thus becomes a very poor receiver of RF energy at the system operating frequency during the transmit pulses.

In the event that the coil is placed in the magnet and the operator neglects to plug in the coil, the PIN diodes function as a passive decoupling system. In this case, the decoupling takes place without the need for the voltage supplied by the MRI system.

Description of electrical isolation of the patient from the surface coil electrical conductors:

The electrical conductors are etched on a flexible circuit board. The circuit board is encased in a plastic housing. The plastic housing wall and/or foam is provided with a minimum of 3 mm thickness. At no time it is possible for the coil conductors to touch the patient. The cable exits the coil inferior to the patient's foot. The cable is of such a length as to reach the MRI system

coil port, but has very little additional length which would allow the cable to become looped or to come in contact with the patient—a potentially hazardous condition. The cable also has an insulating jacket, which increases separation of the cable if it did somehow become looped.

Indications for Use:

The dS FootAnkle 16ch 1.5T Coil is intended to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the foot and ankle that can be interpreted by a trained physician.

Predicate Device Information:

Predicate Device Name	Predicate 510(k) Submission Reference
FAC-63 Foot and Ankle Coil	K050514

Safety and Effectiveness:

The proposed dS FootAnkle 16ch 1.5T Coil labeling contain instructions for use and necessary cautions, warnings and notes to provide for safe and effective use of the device. Risk Management is ensured via Invivo Risk Management procedure, which is used to identify potential hazards. These potential hazards are controlled via the product development process, verification and validation testing and safety features provided by the MRI Scanners.

Technological Characteristics:

The technological characteristics of the proposed dS FootAnkle 16ch 1.5T Coil is exactly the same as the currently marketed and predicate device FAC-63 Foot and Ankle Coil.

The technological characteristic of a receive-only radio frequency (RF) coil is that the coil receives radio frequency signals from the tissue of interest. This technological characteristic of the proposed dS FootAnkle 16ch 1.5T Coil has not changed as compared to the technological characteristic of the currently marketed and predicate device FAC-63 Foot and Ankle Coil.

Based on the information provided above, the proposed dS FootAnkle 16ch 1.5T Coil is considered substantially equivalent to the currently marketed and predicate device FAC-63 Foot and Ankle Coil (K050514) in terms of technological characteristics.

The proposed dS FootAnkle 16ch 1.5T Coil utilizes the same technological characteristic as the predicate FAC-63 Foot and Ankle Coil. Both have similar design, intended use, patient safety features, housing materials, overall dimensions, and operating principals; and substantially equivalent in their performance and effectiveness for their intended uses.

Following is the comparison of technological characteristics between the currently marketed and predicate device FAC-63 Foot and Ankle Coil and proposed dS FootAnkle 16ch 1.5T Coil:

Table-01
Comparison of the Technological Characteristics of the Predicate Device and the Proposed Device

Device Features	Predicate Device K050514 FAC-63 Foot and Ankle Coil	Proposed Device dS FootAnkle 16ch 1.5T Coil	Comments
Indications for Use	To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the foot and ankle that can be interpreted by a trained physician	The dS FootAnkle 16ch 1.5T Coil is intended to be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the foot and ankle that can be interpreted by a trained physician.	Addition of proposed coil name to the indication for use statement does not affect its intent use as well as impact device's safety and effectiveness.
Coil Dimensions Length x Width x Height	12.75 x 7.04 x 11.23 inches	14.46 x 8.13 x 12.65 inches	The change in dimensions is to accommodate more channels. No impact to device safety and effectiveness.
Coil Frequency	63.87 MHz	Identical	No Change
Coil Design	Receive-only, Phased Array	Identical	No Change
Magnetic Field Orientation (B0)	Horizontal	Identical	No Change
Coil Geometry Housing Design	One piece housing	Identical	No Change
Housing Thickness	3mm insulation minimum	Identical	No Change
Decoupling Method	LC Tank Circuit	Identical	No Change
Number of Channels/ Preamplifiers	8 channels / 8 preamplifiers	16 channels / 16 preamplifiers	The number of channels was increased to meet the customer and market needs. No impact to device safety and effectiveness.

Table-01 Comparison of the Technological Characteristics of the Predicate Device and the Proposed Device			
Device Features	**Predicate Device K050514** **FAC-63 Foot and Ankle Coil**	**Proposed Device** **dS FootAnkle 16ch 1.5T Coil**	**Comments**
Housing Material	Lexan 950	Lexan 925	Both are similar materials and have been used in current products. No impact to device safety and effectiveness.
Base Pad	Urethane Foam with Guardian MPGX coating	Urethane Foam with Polyscan Coating	Both are similar materials and have been used in current products. No impact to device safety and effectiveness.
Base Plate Pad	EVA Foam Covered with CFMS	PolyDry Healthcare Fabric Exterior	Both are similar materials with no impact to device safety and effectiveness.
System Connector / Compatibility	ODU CDAS Connector for Philips Scanner	Identical	No Change

Non-Clinical Performance Testing Information:

The proposed dS FootAnkle 16ch 1.5T Coil complies with the following international and FDA-recognized consensus standards:

- IEC 60601-1, 3rd edition
- IEC 60601-2-33, 3rd edition
- ISO 14971, 2nd edition
- ISO 10993-1, 2nd edition
- Device specific draft guidance document, entitled "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices – July 14, 2015"

Bench performance testing includes both non-clinical testing and clinical demonstrations of the representative anatomic region (foot and ankle imaging) using FDA-cleared Philips 1.5T scanner. The non-clinical testing characterizes the Signal-to-Noise Ratio (SNR), Image Quality and special purpose of the RF receive-only coil. The clinical demonstration DICOM images were reviewed by a clinical radiologist to confirm the image quality is adequate. The images

and supporting attestation statements by the radiologist are provided in Appendix 5, Clinical Evaluation.

Non-clinical verification and validation test results demonstrate that the proposed dS FootAnkle 16ch 1.5T Coil

- Complies with the device specifications, identified international and FDA-recognized consensus standards, and device specific guidance document entitled "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices"
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the proposed dS FootAnkle 16ch 1.5T Coil is as safe and effective as the predicate device FAC-63 Foot and Ankle Coil (K050514) in terms of safety and effectiveness.

Summary of Clinical Data:

The proposed dS FootAnkle 16ch 1.5T Coil does not require clinical study since substantial equivalence to the predicate device was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Technological characteristic;
- Non-clinical performance testing; and
- Safety and effectiveness

Conclusion:

The proposed dS FootAnkle 16ch 1.5T Coil is substantially equivalent to the currently marketed and predicate device FAC-63 Foot and Ankle Coil (K050514) in terms of design features, principals of operation, technological characteristic, indications for use, magnetic system compatibility, and safety and effectiveness. Additionally, the non-clinical performance (verification and validation) tests, which complied with the device specifications and requirements specified in the international and FDA-recognized consensus standards demonstrated that the proposed device dS FootAnkle 16ch 1.5T Coil meets the acceptance criteria and is adequate for the established intended use. The electrical isolation methods, decoupling method and housing material are similar for the predicate device.

The results of both non-clinical and device performance tests demonstrate that the proposed device is as safe, as effective, and performs as well as the predicate device.