September 1, 2023

Philips Healthcare (Suzhou) Co., Ltd.
℅ Li Sherry
Regulatory Affairs Specialist
No. 258, Zhongyuan Road
Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K232021
Trade/Device Name: Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: June 12, 2023
Received: July 7, 2023

Dear Li Sherry:

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
DHT8C: 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.

Submission Number *(if known)*

K232021

Device Name

Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T

Indications for Use *(Describe)*

The Smart Fit TorsoCardiac 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the torso (including chest, abdomen, pelvis), head and neck and heart that can be interpreted by a trained physician.

The Smart Fit Shoulder 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the Shoulder 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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K232021

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92(c)]

Date Prepared:	July 04, 2023	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, Zhongyuan Road, Suzhou Industrial Park,Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630	
Primary Contact Person:	Sherry Li Regulatory Affairs Specialist Phone: +86-17849535031 E-mail: sherry.li@philips.com	
Secondary Contact Person	Erhong Wang Senior Manager Regulatory Affairs Phone: +86-512-67336804 E-mail: erhong.wang@philips.com	
Device Name:	Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T	
Classification:	Classification name:	Magnetic Resonance Diagnostic Device
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Magnetic Resonance Diagnostic Device
	Device Class:	Class II
	Primary Product Code:	MOS
Predicate Device for Smart Fit TorsoCardiac 1.5T	Trade name:	dS TorsoCardiac 1.5T
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K212864
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	MOS
Predicate Device for Smart Fit Shoulder 1.5T	Trade name:	1.5T 16 CH GE Shoulder Coils
	Manufacturer:	InVivo Corporation
	510(k) Clearance:	K162001
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	MOS

Device Description:	The proposed of Smart Fit Shoulder 1.5T and Smart Fit TorsoCardiac 1.5T are intended to be used in conjunction with a Philips MR-system to enable trained physicians to obtain cross-sectional images of the internal structure of the head, body, or extremities, in any orientation. These images, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning. The proposed Smart Fit Torsocardiac 1.5T is a phased array receive-only coil for high resolution diagnostic imaging of the torso (including chest, abdomen, pelvis), head and neck and heart. The coil foam is composed of PU foil, flexible PCB and EVA to provide sufficient flexibility along Left-Right direction for patient body scan. The layers from outside to patient side are: PU foil (outer surface), EVA30 foam, PCBA of the coil and PU foil (inner surface). The foam looks flat at the top surface. A few parts, two feed- board boxes, cable housing and a small connector placed across the central Head-Feet axis are also at the top surface. Inner surface is naturally flat and is bendable along slots to fit well to the patient body. The proposed Smart Fit Shoulder 1.5T is a phased array receive-only coil for high resolution diagnostic imaging of shoulder. The coil foam is composed of PU foil, flexible PCB and EVA to provide sufficient flexibility along Anterior-Posterior direction for patient shoulder scan. The layers from outside to patient side are: PU foil (outer surface), EVA30 foam, PCBA of the coil, EVA 30 foam, and PU foil (inner surface). A few parts, feed-board boxes, cable housing and a small connector placed across the Head-Feet axis are also at the outer surface. Inner surface is naturally flat and is bendable along slots to fit well to the patient body.
Indications for Use:	The Smart Fit TorsoCardiac 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the torso (including chest, abdomen, pelvis), head and neck and heart that can be interpreted by a trained physician. The Smart Fit Shoulder 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the Shoulder that can be interpreted by a trained physician.

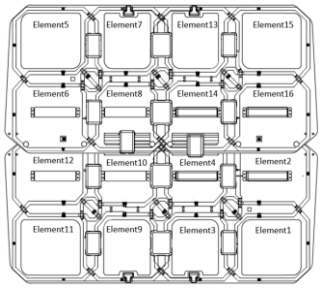
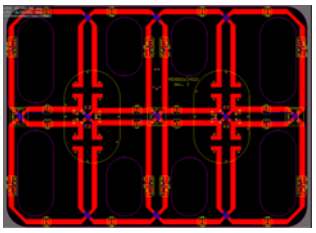
Substantial Equivalence:

The 510(k) summary contains a summary of the technological characteristics of the proposed Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T compared to the predicate devices dS TorsoCardiac 1.5T(K212864) and 1.5T 16CH GE Shoulder Coils(K162001).

Table 1

Comparison of the primary currently marketed and predicate device, dS TorsoCardiac 1.5T versus the proposed Smart Fit TorsoCardiac 1.5T

	Proposed Smart Fit TorsoCardiac 1.5T	Primary Currently Marketed and Predicate Device, dS TorsoCardiac 1.5T	Conclusion
Design features			
Appearance			Similar. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Coil Dimensions Length X Width X Height	LXWXH = 602 X 554 X 25mm	LXWXH = 586 X 503 X 40mm	Similar. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
Number of Channels / Preamplifiers	Sixteen preamplifiers along the cable and sixteen elements distributed in four rows and four columns	Eight preamplifiers inside the coil foam and distributed in two rows and four columns.	Similar. The differences in number of channels and

				distribution of elements between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.	
	Coil Geometry / Housing Design			Similar. The differences in distribution of elements between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.	
	System Connector / Compatibility and coil connector	Analogue connector mating face with dS Interface S 1.5T or dS Interface L 1.5T, which has a DCI connector mating face with the MR system.	Analogue connector mating face with 16ch dS Interface Box (dS Interface S 1.5T or dS Interface L 1.5T) which has a DCI connector mating face with the MR system.	Same	
	Application site / body part	Torso (incl. chest, abdomen, pelvis), head and neck, and heart	Thorax, abdomen, pelvis, cardiac imaging, peripheral vascular imaging, long bones.	Same. Anatomies that can be imaged with the Smart Fit TorsoCardiac can also be imaged with the equivalent device.	
	Patient population	Philips Rx coils are intended for any patient who requires an MR examination, and for whom the use of the coil provides an additional diagnostic benefit (in terms of Field of View or Signal-	Philips MR systems are designed to create images of the head, body or extremities of any patient (prenatal to geriatric) referred to an MR study by a trained physician.	Same. Although the wording is slightly different, the meaning is	

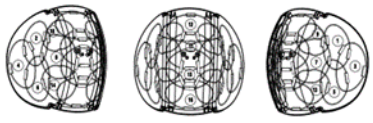
	to-noise ratio) according to the clinical user. Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to coil dimensions.	Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to system capabilities (magnet bore size: 60 cm or 70 cm; mechanical strength of the patient support, allowing 150 kg or 250 kg) and taking into account pre-screening results and contraindications.	the same. The wording for the Smart Fit coils is adapted such that it is more specific to coils. No difference in characteristics between products.
Intended Use			
Intended use	Philips Magnetic Resonance (MR) Receive-only (Rx) coils are intended to be used in conjunction with a Philips MR-system to enable trained physicians to obtain cross-sectional images of the internal structure of the head, body, or extremities, in any orientation. These images, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning.	The Magnetic Resonance (MR) coil is used with an MR scanner. A trained physician interprets the diagnostic images (of the anatomy of interest) produced.	Same. Although the wording is slightly different the meaning is the same. No difference in characteristics between products.
Fundamental Scientific Technology			
Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
Magnetic Field Orientation (B0)	Head-Feet oriented	Head-Feet oriented	Same.
Frequency range	63.87MHz+/-0.75MHz	63.87MHz+/-0.75MHz	Same.
Magnetic Field Orientation (B0)	Head-Feet oriented	Head-Feet oriented	Same.
Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Same.
Energy source	Derived from MR scanner, no internal energy source	Derived from MR scanner, no internal energy source	Same.
Housing Material	PC and PU for Smart Fit TorsoCardiac 1.5T	PC and PU for the dS TorsoCardiac 1.5T;	Same.

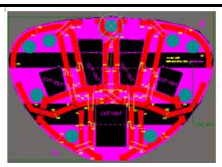
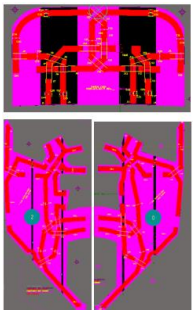
Base Pad	PCB	PCB	Same.
Principle of operation	The coil receives magnetic resonance signals generated in hydrogen nuclei (protons) in the human body while blocking the radio frequency magnetic field applied by the MRI system at specified timings. The received signal is amplified and transmitted to the MRI system, where it is processed into tomographic images by the computer.	The coil receives magnetic resonance signals generated in hydrogen nuclei (protons) in the human body while blocking the radio frequency magnetic field applied by the MRI system at specified timings. The received signal is amplified and transmitted to the MRI system, where it is processed into tomographic images by the computer.	Same.
Critical performance requirements	Philips MR coils fulfill all applicable IEC60601 and IEC60601-2-33 requirements, describing the safety and essential performance requirements for medical devices in general and MR coil specifically.	Philips MR coils fulfill all applicable IEC60601 and IEC60601-2-33 requirements, describing the safety and essential performance requirements for medical devices in general and MR coil specifically.	Same.
Biological characteristics Philips MR RF Rx coils are non-invasive surface devices that are only in contact with covered and/or intact patient skin with limited exposure (<24h). Biocompatibility testing against internal specifications and requirements of the ISO10993-1 has been performed. Further details can be found in the Biocompatibility Report.			
Materials or substances in contact with which human tissues or body fluids*	Intact skin	Intact skin	Same
Kind and duration of contact with which human tissues or body fluids	coils are only in contact with covered and/or intact skin with limited exposure < 24h	coils are only in contact with covered and/or intact skin with limited exposure < 24h	Same
Release characteristics of substances, including degradation products and leachables	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Same

* The characteristic must be the same for the demonstration of equivalence

Table 2

Comparison of the primary currently marketed and predicate device, 1.5T 16CH GE Shoulder Coils versus the proposed Smart Fit Shoulder 1.5T

	Proposed Smart Fit TorsoCardiac 1.5T	Primary Currently Marketed and Predicate Device, 1.5T 16CH GE Shoulder Coils	Conclusion
Design features			
Appearance			Similar. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Coil Dimensions Length X Width X Height	LR direction: 160mm HF direction: 240mm AP direction: 260mm	LR direction: 160mm HF direction: 240mm AP direction: 230mm	Similar. The differences in appearance between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
Number of Channels / Preamplifiers	Sixteen preamplifiers inside the coil foam and symmetrical structure of both wings. There are 6 elements in each wing, and 4 elements arrayed in the middle of the coil.	Sixteen preamplifiers inside the coil foam and 16 elements distributed in top and bottom.	Similar. The differences in distribution of preamplifiers and elements between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
Coil Geometry / Housing Design		Location of elements Anterior Feed:	Similar. The differences in

			 Posterior Feed: 	distribution of elements between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
	System Connector / Compatibility and coil connector	Analogue connector mating face with dS Interface S 1.5T or dS Interface L 1.5T, which has a DCI connector mating face with the MR system.	Connector mating face with dStream interface 1.5T which has a DCI connector mating with the MR system.	Similar. To be compatible with different MRI systems. The difference in system connector/compatibility and coil connector between products are not expected to trigger a clinically significant difference in clinical performance or safety of the device.
	Application site / body part	Shoulder	Shoulder	Same.
	Patient population	Philips Rx coils are intended for any patient who requires an MR examination, and for whom the use of the coil provides an additional diagnostic benefit (in terms of Field of View or Signal-to-noise ratio) according to the clinical user. Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to coil dimensions.	Philips MR systems are designed to create images of the head, body or extremities of any patient (prenatal to geriatric) referred to an MR study by a trained physician. Exceptions to admissible patients relate to their physical characteristics (circumference, mass) in relation to system capabilities (magnet bore size: 60 cm or 70 cm; mechanical strength of the patient support, allowing 150 kg or 250 kg) and taking into account pre-screening results and contraindications.	Same. Although the wording is slightly different, the meaning is the same. The wording for the Smart Fit coils is adapted such that it is more specific to coils. No difference in characteristics between products.
	Intended Use			

	Intended use	Philips Magnetic Resonance (MR) Receive-only (Rx) coils are intended to be used in conjunction with a Philips MR-system to enable trained physicians to obtain cross-sectional images of the internal structure of the head, body, or extremities, in any orientation. These images, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning. (Indications for Use: The Smart Fit Shoulder 1.5T coil is designed to be used in conjunction with a Philips 1.5T MR system to produce diagnostic images of the Shoulder that can be interpreted by a trained physician.)	The 16 Channel Shoulder Coil is to be used in conjunction with Magnetic Resonance Scanners to produce diagnostic images of the shoulder that can be interpreted by a trained physician.	Same. Although the scope of intended use of proposed device looks larger than predicate device, the specific anatomical location is only the shoulder. Details can be found in the Indications for Use of proposed device.
	Fundamental Scientific Technology			
	Type of coil	Phased-array Receive only coil	Phased-array Receive only coil	Same.
	Magnetic Field Orientation (B0)	Head-Feet oriented	Head-Feet oriented	Same.
	Frequency range	63.87MHz+/-0.75MHz	63.87MHz+/-0.75MHz	Same.
	Magnetic Field Orientation (B0)	Head-Feet oriented	Head-Feet oriented	Same.
	Decoupling method	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Overlap, pre-amp decouple, Active/Passive PIN diode decoupling	Same.
	Energy source	Derived from MR scanner, no internal energy source	Derived from MR scanner, no internal energy source	Same.
	Housing Material	PC and PU for Smart Fit Shoulder 1.5T	PC only for 1.5T 16CH GE Shoulder Coils	Similar. The difference in materials between products are not expected to trigger a clinically significant difference in clinical performance or safety

			of the device. The safety of PC and PU has been proved in the biocompatibility report.
Base Pad	PCB	PCB	Same.
Principle of operation	The coil receives magnetic resonance signals generated in hydrogen nuclei (protons) in the human body while blocking the radio frequency magnetic field applied by the MRI system at specified timings. The received signal is amplified and transmitted to the MRI system, where it is processed into tomographic images by the computer.	The coil receives magnetic resonance signals generated in hydrogen nuclei (protons) in the human body while blocking the radio frequency magnetic field applied by the MRI system at specified timings. The received signal is amplified and transmitted to the MRI system, where it is processed into tomographic images by the computer.	Same.
Critical performance requirements	Philips MR coils fulfill all applicable IEC60601 and IEC60601-2-33 requirements, describing the safety and essential performance requirements for medical devices in general and MR coil specifically.	Philips MR coils fulfill all applicable IEC60601 and IEC60601-2-33 requirements, describing the safety and essential performance requirements for medical devices in general and MR coil specifically.	Same.
Biological characteristics Philips MR RF Rx coils are non-invasive surface devices that are only in contact with covered and/or intact patient skin with limited exposure (<24h). Biocompatibility testing against internal specifications and requirements of the ISO10993-1 has been performed. Further details can be found in the Biocompatibility Report.			
Materials or substances in contact with which human tissues or body fluids*	Intact skin	Intact skin	Same
Kind and duration of contact with which human tissues or body fluids	coils are only in contact with covered and/or intact skin with limited exposure < 24h	coils are only in contact with covered and/or intact skin with limited exposure < 24h	Same
Release characteristics of substances, including degradation products and leachables	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Due to the nature of body contact of Rx coils, degradation is not considered a recommended endpoint for consideration of biocompatibility.	Same

* The characteristic must be the same for the demonstration of equivalence

	Based on the information provided above, Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T are considered substantiall equivalent to the primary currently marketed and predicate device dS TorsoCardiac 1.5T(K212864) and 1.5T 16CH GE Shoulder Coils(K162001).
Summary of Non-Clinical Performance Data:	The proposed Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T complies with the following international and FDA-recognized consensus standards: • ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA/CDRH recognition number 19-46 • IEC60601-2-33 Ed. 3.2:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis FDA/CDRH recognition number 12-295 • IEC0601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests FDA/CDRH recognition number 19-36 • IEC60601-1-6 Edition 3.1:2013 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA/CDRH recognition number 5-89 • ISO 14971 Ed. 3:2019 Medical devices – Application of risk management to medical devices. FDA/CDRH recognition number 5-125. • IEC 62366 Edition 1.1: 2020-06 CONSOLIDATED VERSION–Medical devices Part 1: Application of usability engineering to medical devices FDA/CDRH recognition number 5-129 • ANSI AAMI ISO10993-1:2018 – Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process FDA/CDRH recognition number 2-258

	• NEMA MS 1-2008(R2020) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging FDA/CDRH recognition number 12-188 • NEMA MS 3-2008 (R2020) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-187 • NEMA MS 9-2008 (R2020) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-288 • NEMA MS 14-2019 Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems FDA/CDRH recognition number 12-331 The performance test results demonstrate that the proposed Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T meets the acceptance criteria and adequate for its intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable. Based on the supporting data provided in this 510(k) submission, the proposed Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T are considered substantially equivalent to the currently marketed and predicate device dS TorsoCardiac 1.5T(K212864) and 1.5T 16CH GE Shoulder Coils(K162001) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T did not require clinical study since substantial equivalence to the legally marketed predicate device was proven in the comparison in terms of safety and effectiveness. All clinical images on the proposed coils Smart Fit TorsoCardiac 1.5T and Smart Fit Shoulder 1.5T were evaluated by qualified radiologists. No issues with the clinical image quality was seen and images were considered have sufficient quality for diagnostic use.