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K964854

ATTACHMENT VIII

SMDA 510(K) SUMMARY



510(k) SUMMARY
MEDRAD PHASED ARRAY 1.5T SHOULDER IMAGING SURFACE COIL

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CLASSIFICATION NAME: Magnetic Resonance Diagnostic Accessory[21 CFR 892.1000}

COMMON/USUAL NAME: MRI Surface Coil

PROPRIETARY NAME: Medrad Phased Array 1.5T Shoulder Imaging Surface Coil

PREDICATE DEVICES: Medrad Phased Array 1.5T Shoulder Imaging Surface Coil - K960901

DEVICE DESCRIPTION:

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is a rigid RF receive only magnetic field pickup coil that is designed to enhance imaging of the human shoulder and the upper and lower extremities. It consist of an anterior and posterior coils which interfaces with the multi-coil port on the GEMS Signa System. The coil is intended for use in all imaging planes, with a field of view(FOV) of at least 12 centimeters and less than 25 centimeters.

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is designed to provide high resolution diagnostic images under the supervision of a physician who is trained in the field of Diagnostic Magnetic Resonance Imaging.

The ABS outer housing of the coil has been designed to provide an enduring enclosure for the coil electrical components. Durability tests are conducted to verify the integrity of the coil structure. Additionally, the coil will not contain any ferrous nickel, ferrite or other magnetic materials which would negatively impact coil performance. The coil is also designed to assure that the components of the coil that come into contact with the patient will not have surface temperatures exceeding 41 degrees Celsius as a result of heating due to dielectric losses.



DEVICE DESCRIPTION (cont.):

Medrad, Inc. believes the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is substantially equivalent to the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil identified in 510(k) - K960901. The proposed Phased Array 1.5T Shoulder Imaging Surface Coil is the same coil that was determined Substantially Equivalent in 510(k) - K96090. This 510(k) is being submitted for addition of upper and lower extremities imaging to the Intended Use of the device and for the addition of an optional third coil (posterior paddle) to the device.

INTENDED USE:

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is for use only with the GEMS family of Super Conductor MR Systems. An anterior loop pair is combined with a posterior loop. The coil is designed to receive RF excitation from the protons of the hydrogen nuclei as a result of the scanner exciting these protons. The coil is designed for anatomical imaging of shoulder region and the upper and lower extremities with a specific size and shape to facilitate placement on the anatomy area of interest. This placement results in a higher Signal To Noise Ratio (SNR) in the region near the surface coil. The greater SNR permits more effective imaging through the use of a smaller FOV and thinner slices.

The intended ROI for imaging includes the anterior and posterior musculoskeletal area of the shoulder and the upper and lower extremities.

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is intended to aid physician diagnosis in the shoulder, upper, and lower extremity regions.

Patient fitness and suitability for MRI must be determined by the individual physician trained in the field of Diagnostic Magnetic Resonance Imaging.

**TECHNOLOGICAL CHARACTERISTICS
COMPARISON WITH PREDICATE DEVICES:**

PHASED ARRAY SHOULDER COIL	PHASED ARRAY SHOULDER COIL
Proposed Device	K960901 - Predicate Device
Compatible with GE 1.5T Signa, Super Conductor Scanners - Phased Array Architecture.	Same
Receive only dual loop anterior phased array coil.	Receive only dual loop anterior phased array coil with an optional third loop - posterior coil.
Plugs into GE Signa System via Phased Array quick disconnect port.	Same
No external tuning or matching is necessary.	Same
<u>Intended Uses:</u> Anatomical Region - Shoulder Nuclei Excited - Hydrogen 2D and 3D Imaging	<u>Intended Uses:</u> Anatomical Region - Shoulder, Upper and lower extremities Nuclei Excited - Hydrogen 2D and 3D Imaging
PATIENT CONTACTING MATERIALS COMPARISON INFORMATION	
ABS	ABS
Velcro Hook/ Latch Fastener	Velcro Hook/ Latch Fastener



PERFORMANCE TEST DATA:

SIGNAL TO NOISE RATIO(SNR):

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil was evaluated using National Electric Manufacturer's Association (NEMA) Standard No. 6, Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images.

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil was evaluated with a loaded phantom to determine the SNR.

IMAGE NON-UNIFORMITY TESTING:

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil was evaluated using NEMA Standards to characterize the non-uniformity of the proposed coil. Contours of the images obtained with the coil were constructed for the axial image, sagittal image, and the coronal image.

TEMPERATURE RISE AND DIELECTRIC STRENGTH SAFETY TESTS:

Safety tests were conducted to present temperature rise test results under moderate duty cycle scan conditions, and also to produce IEC 601-1 dielectric strength test results.

CLINICAL TESTING:

Images were obtained with the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil to substantiate equivalent SNR and morphological detail with the predicate coil.

CONCLUSION:

Extensive safety, verification, durability, and clinical testing was conducted with the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil to substantiate the claims of the proposed device and to verify that the proposed device is substantially equivalent to the predicate device.

Image clarity, morphological detail and increased SNR demonstrate that the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil will produce the required detailed resolution in surface coil imaging .