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510(k) SUMMARY

MEDRAD PHASED ARRAY 1.5T SHOULDER IMAGING SURFACE COIL

OFFICIAL CONTACT: Rodney J. Rylands
Medrad, Inc.
P.O. Box 780, Medrad Drive
Indianola, PA 15051
(412) 967-9700 Ext. 3778

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: GE Shoulder Coil - K892235
GE Phased Array Breast Coil

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 associated anatomic region. It consist of an anterior loop contoured to comfortably fit the anterior aspect of the right or left shoulder. The anterior loop cable 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.):

In summary, the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil utilizes a combination of the proven phased array technology of previous MRI surface coils such as the predicate Signa Phased Array 1.5T Breast Imaging Surface Coil, and the equivalent anatomical region surface imaging as demonstrated with the predicate Signa Linear 1.5T Shoulder Coil.

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 either the right or left shoulder region 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. This includes the rotator cuff, humeral head, glenoid, glenoid labrum and glenoid cavity. The region runs superior through the clavicle and acromion and inferior through the infraspinatus. It also extends posterior to the lateral margin.

The Medrad Phased Array 1.5T Shoulder Imaging Surface Coil is intended for use in physician diagnosis of impingement syndrome, glenoid labrum tendon tears, rotator cuff tears, edema secondary to the aforementioned, retraction of the supraspinatus muscle and trauma of the long head of the biceps tendon.

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	LINEAR SHOULDER COIL	PHASED ARRAY BREAST COIL
Proposed Device	Predicate Device - K892235	Predicate Device - K923025
Compatible with GE 1.5T Signa, Super Conductor Scanners - Phased Array Architecture.	Compatible with GE 1.5T Signa, Super Conductor Scanners.	Compatible with GE 1.5T Signa, Super Conductor Scanners - Phased Array Architecture.
The intended Region of Interest for imaging includes the anterior and posterior musculoskeletal area of the shoulder including the rotator cuff, humeral head, glenoid, glenoid labrum and glenoid cavity.	The intended Region of Interest for imaging includes the anterior and posterior musculoskeletal area of the shoulder including the rotator cuff, humeral head, glenoid, glenoid labrum and glenoid cavity.	The intended Region of Interest for imaging includes the breast, nipple, chest wall and auxiliary tissue.
Receive only dual loop phased array coil.	Receive only single loop linear coil.	Receive only dual loop phased array coil.
Plugs into GE Signa System via Phased Array quick disconnect port.	Plugs into GE Signa System via Head port quick disconnect adapter.	Plugs into GE Signa System via Phased Array quick disconnect port.
No external tuning or matching is necessary.	No external tuning or matching is necessary.	No external tuning or matching is necessary.
<u>Intended Uses:</u> Anatomical Region - Shoulder Nuclei Excited - Hydrogen 2D and 3D Imaging	<u>Intended Uses:</u> Anatomical Region - Shoulder Nuclei Excited - Hydrogen 2D and 3D Imaging	<u>Intended Uses:</u> Anatomical Region - Breast Nuclei Excited - Hydrogen 2D and 3D Imaging
PATIENT CONTACTING MATERIALS COMPARISON INFORMATION		
ABS	ABS	ABS
Velcro Hook/ Latch Fastener	Velcro Hook/ Latch Fastener	Velcro Hook/ Latch Fastener
N/A	Closed Cell Foam Type 2AS FR	Vinyl/Denier Nylon/ Recitichel Foam
N/A	Polystyrene Sheet	Disposable Liner

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.

Both the Medrad Phased Array 1.5T Shoulder Imaging Surface Coil and the predicate Linear Surface coil were evaluated with a loaded phantom to determine the SNR for both coils. Both coils were evaluated using the same scan parameters to produce identical images. The results were compared to verify the increased SNR of the proposed coil

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 for both the proposed Medrad Phased Array 1.5T Shoulder Imaging Surface Coil and the predicate Linear 1.5T Shoulder Coil and the results were compared to substantiate improved SNR and morphological detail with the proposed 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 devices.

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 .