

K98 4159

JAN 12 1999

**510(k) SUMMARY**  
**MEDRAD 0.5T, 1.0T QUAD CTL COILS**

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

**COMMON/USUAL NAME:** MR Imaging Surface Coil

**PROPRIETARY NAME:** Medrad Quadrature CTL Array Coil

**PREDICATE DEVICES:** Hitachi Quad C-Spine  
General Electric (GE) Quad T/L with Positioner  
Coil  
Medrad Phased Array Shoulder Coil

**DEVICE DESCRIPTION:**

The Medrad Quad CTL Array Coil is a **receive only** coil designed to enhance the MR Imaging of the thoracic and lumbar regions of the spine anatomy.

**INTENDED USE:**

The Medrad Quadrature CTL Coil is a **receive only coil** intended to be used with the General Electric Superconducting MRI Scanners. This coil is intended to facilitate complete MR imaging of the cervical, thoracic and lumbar regions of the spine without need of patient repositioning of the device.

Anatomical Region: cervical, thoracic and lumbar regions of the spine anatomy.

Nuclei Excited: Hydrogen

Diagnostic Uses: 2D and 3D Imaging

**Proposed Medrad Quad CTL Coil**  
**Technical Comparison To Predicate Devices:**

The following table compares claims made in regard to the Hitachi Quad C-Spine Coil and the Medrad Quad CTL Coil.

<b>Hitachi Quad C-Spine Coil (K954952)</b>	<b>GE Quad T/L w/ Positioner Coil (K902663)</b>	<b>Medrad PA Shoulder Coil (K960901)</b>	<b>Medrad Quad CTL Coil</b>
Receive-only Quadrature coil	Receive-only Quadrature coil	Receive-only, Phased Array Coil	Receive-only, Phased Array Quadrature coil.
Region of interest includes the area superior to the top of the sella turcica and inferior to the third thoracic vertebrae. Included is the brachial plexus region, nerve roots and CSF.	Region of interest includes the thoracic and lumbar regions of the spine.	N/A	Region of interest includes the cervical, thoracic, and lumbar regions of the spine.
The Quad C-Spine Coil is compatible with the MRH-1500 and Stratis system pulse sequences and imaging options.	The quad T/L w/ Positioner coil is compatible with all Signa and Contour System pulse sequences and appropriate imaging options.	The PA Shoulder coil is compatible with all Signa System pulse sequences and appropriate imaging options.	The quad CTL coil is compatible with all Signa and Contour System pulse sequences and appropriate imaging options.
No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.
The coil plugs into the system via three BNC connectors	The coil plugs into a common slip connector.	The coil uses a Bendix connector for the MRI Scanner interface.	The coil uses a Bendix connector for the MRI Scanner interface.

**Proposed Medrad Quad CTL Coil**  
**Technical Comparison to Predicate Devices (Cont.):**

<b>Patient contacting materials comparison information</b>		
<b>Hitachi Quad C-Spine Coil</b>	<b>GE Quad T/L w/ Positioner Coil Medrad PA Shoulder Coil</b>	<b>Medrad Quad CTL Coil</b>
The housing material is made from Royalite ABS, Fire Rated UL94V-0	The housing material is made from Royalite ABS, Fire Rated UL94V-0	The housing material is made from Polyurethane 30% Glass Filled, Fire Rated UL 94.5V
Comfort pad material is made of Unifoam S82N, Fire Rated UL 94 HF-1 with a PVC Film vinyl film fire rated cover.	Comfort pad material is made of Recticel Foam (6 lb. density, Fire Rated UL 94V HF1 with a PVC Film vinyl or Nylon fire rated cover.	Comfort pad material is made of Unifoam S82N, Fire Rated UL 94 HF-1 with a Nylon cover, Fire Rated CPAI-84.

## PERFORMANCE TEST DATA:

SIGNAL TO NOISE RATIO (SNR) - A Signal to Noise Ratio(SNR) study was conducted to generate a Signal -To-Noise ratio of the proposed Medrad 1.0T QUADRATURE CTL ARRAY Coil. Due to the different platforms of the predicate devices, a direct comparison between the proposed device and the predicate devices could not be completed.

IMAGE UNIFORMITY - The Medrad Quad CTL Array 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.

GEOMETRIC DISTORTION: None. Static magnetic field distortion results from the use of magnetic materials in the construction of a surface coil. This device contains slightly magnetic materials or components. However, such components have been positioned within the surface coil so that no observable distortion of the static magnetic field is present.

TRANSMIT RF FIELD [B1] DISTORTION - Analysis of the electrical design of the coil and its blocking network demonstrates that no significant currents are induced. No artifacts of any type were observed during imaging.

RESOLUTION, SLICE THICKNESS, AND CONTRAST - These performance parameters are not affected by the use of a surface coil and were not separately tested in the performance evaluation of the proposed Medrad Quad CTL Array Coil.

CLINICAL EVALUATION - Clinical images for the proposed 1.0T Quad CTL Array Coil have been provided with this submission to demonstrate the clinical effectiveness of the Quad CTL Array coils. Based on these results, and the SNR results for the proposed 1.0T Quad CTL Array Coils, Medrad concludes that the 0.5T and 1.0T Quad CTL Array Coils will produce similar clinical image results.

CONCLUSION - Extensive safety, verification, durability and clinical testing was conducted on the predicate GE and/or Hitachi devices. **(K954952, K902663 and K960901)** The proposed device is deemed by Medrad to be substantially equivalent.



JAN 12 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Jim Ferguson, Jr.  
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Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051Re: K984159  
Medrad Quadrature CTL Array Coil  
Dated: November 18, 1998  
Received: November 19, 1998  
Regulatory class: II  
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Ferguson:

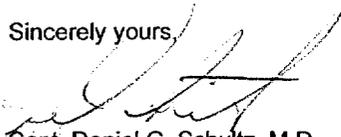
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
Capt. Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K98 4159

DEVICE NAME: Medrad Quad CTL Array Coil

INDICATIONS FOR USE:

The Medrad Quad CTL Array Coil is a receive only coil intended to be used MRI Scanner Systems for imaging of the cervical, thoracic and lumbar regions of the spine anatomy.

The Medrad Quad CTL Array Coil is intended for use only under the supervision of a physician who is trained in the field of Diagnostic Magnetic Resonance Imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use                        
(Per 21 CFR 801.109)

OR

Over-The Counter-Use                       
(Optional Format 1-2-96)

David G. Segura  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K984159