

NOV 3 1998

K982959

**510(k) SUMMARY**  
**MEDRAD 1.0T, 1.5T QUAD C-SPINE 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 Quad C-Spine Coil

**PREDICATE DEVICES:** General Electric (GE) Linear C-Spine  
Hitachi Quad C-Spine Coil

**DEVICE DESCRIPTION:**

The Medrad Quad C-Spine Coil is a receive only coil designed to enhance the MR Imaging of 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.

**INTENDED USE:**

The Medrad Shoulder 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 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

**Anatomical Region:** 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

**Nuclei Excited:** Hydrogen

**Diagnostic Uses:** 2D and 3D Imaging

**Proposed Medrad Quad C-Spine Coil  
 Technical Comparison To Predicate Devices:**

The following table compares the predicate GE Linear C-Spine Coil, the Hitachi 1.5T Quad C-Spine Coil and the proposed Medrad Quad C-Spine Coil.

<b>GE Linear C-Spine Coil (K884369)</b>	<b>Hitachi Quad C-Spine Coil (K954952)</b>	<b>Medrad Quad C-Spine Coil</b>
Receive-only linear coil.	Receive-only Quadrature coil	Receive-only 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 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 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.
The linear C-Spine coil is compatible with all GE Signa System pulse sequences and appropriate imaging options.	The Quad C-Spine Coil is compatible with the MRH-1500 and Stratis system pulse sequences and imaging options.	The quad C-Spine coil is compatible with all GE Signa 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.
The coil plugs into a common slip connector.	The coil plugs into the system via three BNC connectors	The coil plugs into a common slip connector.

**Proposed Medrad Quad C-Spine Coil  
 Technical Comparison to Predicate Devices (Cont.):**

<b>Patient contacting materials comparison information</b>		
<b>GE Linear C-Spine Coil</b>	<b>Hitachi Quad C-Spine Coil</b>	<b>Medrad Quad C-Spine Coil</b>
The housing material is made from Royalite ABS, Fire Rated UL 94V-0	The housing material is made from Royalite ABS, Fire Rated UL 94V-0	The housing material is made from Royalite ABS, Fire Rated UL 94V-0
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 Unifoam S82N, Fire Rated UL 94 HF-1 with a PVC Film vinyl film fire rated cover.	Comfort pad material is made of Unifoam S82N, Fire Rated UL 94 HF-1 with a PVC Film vinyl film fire rated cover.

## PERFORMANCE TEST DATA:

### SIGNAL TO NOISE RATIO (SNR)

A Signal to Noise Ratio(SNR) study was conducted to generate a Signal -To-Noise ratio comparison between the proposed Medrad Quad C-Spine coil and the predicate Hitachi Quad C-Spine (K954952) and the General Electric Linear C-Spine (K884369).

IMAGE UNIFORMITY - The Medrad Quad C-Spine 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 and 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 Shoulder Coil.

CLINICAL EVALUATION - Images were obtained for the proposed Medrad Shoulder Coil. The clinical images of the predicate devices may be found in their respective 510(k) submissions.

CONCLUSION - Extensive safety, verification, durability and clinical testing was conducted on the predicate devices. **(K884369 and K954952)**. The proposed device is deemed by Medrad to be substantially equivalent.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Jim Ferguson, Jr.  
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Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051Re: K982959  
Medrad Quad C-Spine Coil  
Dated: August 21, 1998  
Received: August 24, 1998  
Regulatory class: II  
21 CFR 892.1000/Procode: 90 LNH

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 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 (Pre-market 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,

Lillian Yin, Ph.D.  
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 2959

DEVICE NAME: Medrad Quad C-Spine Coil

INDICATIONS FOR USE:

The Medrad Quad C-Spine Coil is a receive only coil intended to be used MRI Scanner Systems for imaging of the Area superior to the top of the sella turcica and inferior to the third thoracic vertebra

The Medrad Quad C-Spine 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 X  
(Per 21 CFR 801.109)

OR

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

David G. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K98 2959