JAN 25 1999

K984257

510(k) SUMMARY
MEDRAD 1.5T PHASED ARRAY NEUROVASCULAR COIL

OFFICIAL CONTACT: Jim Ferguson, Jr.
Sr. Regulatory Affairs Associate
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 Ext. 3326

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

COMMON/USUAL NAME: MR Imaging Surface Coil

PROPRIETARY NAME: Medrad Phased Array Neurovascular Coil

PREDICATE DEVICES: Medrad Neurovascular Coil
Medrad Phased Array Shoulder Coil

DEVICE DESCRIPTION:

The Medrad Phased Array Neurovascular Coil is **a receive only**, phased array coil designed to enhance the MR Imaging of the head and neck 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 will facilitate complete MR imaging of the intracranial/extracranial Neurovascular, skull base and C-Spine without need for repositioning the coil on the patient.

Anatomical Region:	intracranial/extracranialNeurovascular, skull base and C-Spine
Nuclei Excited:	Hydrogen
Diagnostic Uses:	2D and 3D Imaging

Proposed Medrad 1.5T Neurovascular Array Coil
Technical Comparison To Predicate Device:

The following table compares claims made in regard to the Medrad 1.5T Neurovascular Coil to the Medrad 1.5T Neurovascular Array Coil

Medrad 1.5T Neurovascular Coil (K981094)	Medrad Phased Array Shoulder Coil (K960901)	Medrad 1.5T Neurovascular Array Coil
Quadrature Transmit-Receive Coil	Phased Array Receive-Only Coil	Phased Array Receive-only Quadrature coil.
Region of interest covers the top of the brain to the aortic arch.	*N/A	Region of interest covers the top of the brain to the aortic arch.
The Neurovascular coil is compatible with all Signa System pulse sequences and appropriate imaging options.	*N/A	The Neurovascular Array coil is compatible with all 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.	*N/A	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.
The coil plugs into the MRI System by way of the Head Coil quick disconnect port	*N/A	The coil plugs into the MRI System by way of the Phased Array quick disconnect port

* This predicate device is being used to substantiate the *technology* equivalence to the proposed device only.

Proposed Medrad 1.5T Neurovascular Array Coil
Technical Comparison to Predicate Devices (Cont.):

Patient contacting materials comparison information	
Medrad 1.5T Neurovascular Coil	**Medrad 1.5T Neurovascular Array Coil**
The housing material is made from Glass Filled Polyester; Fire Rated UL 94V-0	The housing material is made from Glass Filled Polyester; Fire Rated UL 94V-0 and Kydex, Fire Rated UL 94V-0
Comfort pad material is made with a Buellidyne coating and are fire rated UL-94 HFI.	Comfort Pad material is made with a cotton material embedded with urethane and is fire rated to CAL 117

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 1.5T PHASED ARRAY NEUROVASCULAR Coil and the predicate Neurovascular device.

IMAGE UNIFORMITY - The Medrad PHASED ARRAY NEUROVASCULAR coil was evaluated using NEMA Standards to characterize the uniformity of the proposed coil. Contours of the images obtained with the coil were constructed for the axial image, sagittal image and coronal images.

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 PHASED ARRAY NEUROVASCULAR.

CLINICAL EVALUATION - Clinical images for the proposed 1.5T PHASED ARRAY NEUROVASCULAR have been provided with this submission to demonstrate the clinical effectiveness of the PHASED ARRAY Neurovascular.

CONCLUSION - Extensive safety, verification, durability and clinical testing was conducted on the predicate Medrad devices. **(K960901, K981094)** The proposed device is deemed by Medrad to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Jim Ferguson, Jr.
Sr. Regulatory Affairs Associate
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051-0780

Re: K984257
Medrad 1.5T Phased Array Neurovascular Coil
Dated: November 25, 1998
Received: November 30, 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

INDICATION FOR USE

510(k) Number: K984257

Device Name: Medrad 1.5T Phased Array Neurovascular Coil

Indications for Use/Intended Use:

The Medrad Phased Array Neurovascular Coil is **a receive only**, phased array coil designed to enhance the MR Imaging of the head and neck anatomy.

The Medrad Phased Array Neurovascular 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984257

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)