JUN 18 1998

K981094

510(k) SUMMARY
MEDRAD .5T, 1.0T, 1.5T NEUROVASCULAR COILS

OFFICIAL CONTACT: Rodney J. Rylands
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CLASSIFICATION NAME: Magnetic Resonance Diagnostic Accessory[21 CFR 892.1000]

COMMON/USUAL NAME: MR Imaging Surface Coil

PROPRIETARY NAME: Medrad Neurovascular Coil

PREDICATE DEVICES: General Electric (GE) Quadrature Head Coil and GE Anterior Neck Coil

DEVICE DESCRIPTION: The Medrad Neurovascular Coil is quadrature transmit / receive coil designed to enhance the MR Imaging of the head and neck anatomy. Reference FIGURE 1 Below:

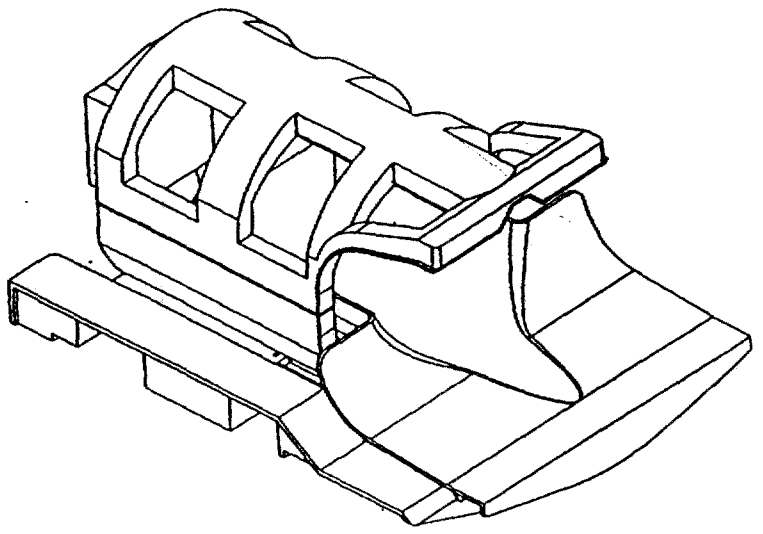

FIGURE 1 - NEUROVASCULAR COIL

INTENDED USE:

The Medrad Neurovascular Coil is a quadrature transmit / receive coil intended to be used with the General Electric Superconducting MRI Scanners. This coil is intended to facilitate complete MR imaging of the intracranial/extracranial neurovasculature and skull base.

Anatomical Region:	Head and Neck, from the top of the cranium to the arch of the aorta.
Nuclei Excited:	Hydrogen
Diagnostic Uses:	2D and 3D Imaging

PROPOSED MEDRAD NEUROVASCULAR COIL TECHNICAL COMPARISON TO PREDICATE DEVICES:

The following table compares claims made in regard to the GE Head Coil, the GE Anterior Neck Coil, and the Neurovascular Coil.

GE Head Coil	GE Anterior Neck Coil	Neurovascular Coil
Predicated Device	Predicate Device	Proposed Device
Quadrature Transmit/Receive Birdcage Coil	Receive-only linear coil.	Quadrature Transmit/Receive coil.
Suggested application: Head	Anterior fossa of the skull base, the orapharynx, larynx, pharynx, and peripharyngeal areas as well as extending down through the sterno-clavicular area.	Coverage extends from the top of the head through the aortic arch.
The Head Coil is compatible with all Signa, Vectra and Contour System pulse sequences.	The anterior neck coil is compatible with all Signa and Contour System pulse sequences and appropriate imaging options.	The coil is compatible with all Signa, and Contour pulse sequences and options.
Each system is tuned to the Head Coil.	No external tuning, or matching, is necessary since the coil is matched to the recommended anatomy of interest.	No external tuning and matching is required.
Plugs into MRI system by way of the Head Coil quick disconnect port.	The coil plugs into a common slip connector.	The coil plugs into the MRI system by way of the Head Coil quick disconnect port.

PROPOSED MEDRAD NEUROVASCULAR COIL TECHNICAL COMPARISON TO PREDICATE DEVICES(Cont.):

Patient contacting materials comparison information		
GE Head Coil	GE Anterior Neck Coil	Neurovascular Coil
The housing material is made from Glass Filled Polyester; Fire Rated UL94-V0	The housing material is made from Closed Cell Polyetheylene Foam; Fire Rated UL94-HF-1	The housing material is made from Glass Filled Polyester; Fire Rated UL94-V0
The comfort pad is made of Denier Nylon Gray (Fire Rated)	No comfort pads	Comfort pads are included made with a Buellidyne coating and are fire rated UL-94 HFI.
Certification: **Medrad, Inc. certifies that the patient contacting materials and formulations for the proposed Medrad Neurovascular Coils are unchanged from currently marketed devices.**		

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 Neurovascular Coil and the predicate GE Head Coil in the Head Position and between the Neurovascular Coil and the predicate Anterior Neck Coil for the Neck location.

IMAGE UNIFORMITY - The Medrad Neurovascular 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.

SPECIFIC ABSORPTION RATE - An SAR analysis data has been gathered for the proposed Medrad Neurovascular Coil per the methodology of NEMA Standards for the following loading cases:

1. Lossless phantom - for determination of coil losses - representing a limit minimum load case.
2. Neck - for determination of RF power deposition during Head and Neck imaging - representing a heavy load.
3. Head - for determination of RF power deposition during Head imaging - representing a light load.

GEOMETRIC DISTORTION: The proposed Medrad Neurovascular 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 Neurovascular Coil.

CLINICAL EVALUATION - Images were obtained for the proposed Medrad Neurovascular Coil and the predicate GE Head Coil and GE Anterior Neck coil. The results wre compared to substantiate equivalency with regards to morphological detail and SNR.

CONCLUSION - Extensive safety, verification, durability, and clinical testing was conducted with the Medrad Neurovascular 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 Neurovascular Coil will produce the required detailed resolution in surface coil imaging .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1998

Rodney J. Rylands
Manager, Regulatory Affairs
Medrad, Inc.
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Re: K981094
Medrad 0.5T, 1.0T and 1.5T Neurovascular Coils for GE Signa MRI Systems
Dated: March 24, 1998
Received: March 26, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Rylands:

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 (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,

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): K981094

DEVICE NAME: Medrad Neurovascular Coil

INDICATIONS FOR USE:

The Medrad Neurovascular Coil is a quadrature transmit/receive coil intended to be used MRI Scanner Systems for imaging of the brain, skull base, and soft tissues of the neck and upper chest, including the carotid arteries and attendant vascular system.

The Medrad 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)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981094