NOV 8 2002

K023596

Special 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Medrad Inc.
Submitter's Address:	One Medrad Drive, Indianola, PA 15051 USA
Telephone Number:	(412) 767-2400, ext. 3326
Fax Number:	(412) 767-2475
Contact Person:	Jim Ferguson, Jr.
Date:	October 25, 2002
Proprietary Name:	Medrad 8-Receiver Phased Array Neurovascular Coil
Common Name:	MR Imaging Surface Coil
Classification:	Class II, 892.1000
Classification Name:	Magnetic Resonance Diagnostic device
Predicate Device:	Medrad 1.5T Phased Array Neurovascular Coil K984257

Substantial Equivalence: The information provided in this premarket notification demonstrates that the proposed device is substantially equivalent to a legally marketed device. The proposed 8-Receiver Phased Array Neurovascular Coil is substantially equivalent to the 1.5T Phased Array Neurovascular Coil (K984257)

The Medrad 8-Receiver Phased Array Neurovascular Coil maintains the same intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate device.

Like the Medrad 4-Receiver Neurovascular Coil, the Medrad 8-Receiver Neurovascular Coil is a receive-only coil intended to be used with the General Electric Superconducting MRI scanners for MR imaging of the intracranial/extracranial Neurovascular, skull base and C-Spine without moving the patient or the coil, i.e., no scan room intervention

Medrad has established, as part of its Quality System, design controls in compliance with FDA's Quality System Regulations (QSRs). These design controls are applied to all Medrad product development processes and product design changes. These design controls were applied to the development of the Stellant CT Injector and meet the requirements of the FDA's QSRs.

As part of the design control a risk analysis was performed, and design verification and validation testing was conducted to support the conclusion drawn by the risk analysis.

Test results demonstrate that the design specifications for the Medrad 8-Receiver Phased Array Neurovascular Coil were met and that the Medrad 8-Receiver Phased Array Neurovascular Coil meets the applicable requirements of the international standards cited. Therefore, it has been determined that the Medrad 8-Receiver Phased Array Neurovascular Coil is substantially equivalent to the predicate device, its predecessor, for its intended use when used as prescribed in the User Operation Manual.

A comparison of features and principles of operation between the proposed device and predicate device is provided in the table below.

Feature	(Proposed) Medrad 1.5T 8-Receiver Neurovascular	Medrad 1.5T Neurovascular Array Coil (Predicate)
Coil type	Phased Array Receive-Only Coil	Phased Array Receive-only Quadrature coil.
Region of Interest	Vertex of the skull to the aortic arch.	Vertex of the skull to the aortic arch.
Compatibility	All phased array GEMS 1.5T Signa Excite platforms with 8-Receiver capability. All Signa System pulse sequences and appropriate imaging options.	All phased array GEMS 1.5T Signa Horizon platforms All Signa System pulse sequences and appropriate imaging options excluding parallel imaging.
Tuning	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.
System connection	The coil plugs into the MRI System by way of the Phased Array quick disconnect port	The coil plugs into the MRI System by way of the Phased Array quick disconnect port
Imaging configurations	High resolution Head, Parallel imaging Fast Brain, Neurovascular, C-Spine (user optional), Volume Neck (user optional), High resolution Head and C-Spine (user optional)	High resolution Head, Fast Brain, Neurovascular, C-Spine (user optional), Volume Neck (user optional), High resolution Head and C-Spine (user optional)

Patient contacting materials comparison information		
	Medrad 1.5T 8-Receiver Neurovascular (Proposed)	**Medrad 1.5T Neurovascular Array Coil (Predicate)**
Housing	The housing material is made from Polyurethane; Fire Rated UL 94V-0	The housing material is made from Glass Filled Polyurethane; Fire Rated UL 94V-0 and Kydex, Fire Rated UL 94V-0
Comfort Pad	Comfort Pad material is made with a cotton material embedded with urethane and is fire rated to CAL 117	Comfort Pad material is made with a cotton material embedded with urethane and is fire rated to CAL 117

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Mr. Jim Ferguson, Jr.
Regulatory Affairs Analyst
Medrad, Inc.
One Medrad Drive
INDIANOLA PA 15051

Re: K023596
Trade/Device Name: Medrad 8 Receiver Phased Array Neurovascular Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: October 25, 2002
Received: October 28, 2002

Dear Mr. Ferguson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Intended Use

Indications for Use Statement

510(k) Number: K023596

Device Name: Medrad 8-Receiver Phased Array Neurovascular Coil

Indications for Use:

The Medrad Phased Array Neurovascular coil is a receive-only coil intended to be used with the General Electric Superconducting MRI scanners. The coil will facilitate complete MR imaging of the intracranial/extracranial Neurovascular, skull base and C-Spine without moving the patient or the coil, i.e., no scan room intervention.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023596

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