

K97 4308

MEDRAD®

JAN 27 1998

QA-97-1222

510(k) SUMMARY

MEDRAD 1.5T PERIPHERAL VASCULAR ARRAY

Medrad, Inc.
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(412) 767-2400

OFFICIAL CONTACT: Mary Ann Greenawalt, J.D.
Sr. Regulatory Affairs Associate
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051

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

COMMON/USUAL NAME: MRI Surface Coil

PROPRIETARY NAME: Medrad 1.5T Peripheral Vascular Array

PREDICATE DEVICES: GE Signa 1.5T Body Coil

DEVICE DESCRIPTION:

The Peripheral Vascular Array is primarily designed for imaging of the vascular structures of the abdomen, pelvis, and lower limbs. Soft tissue imaging of these areas may also be evaluated using this device. The design of this coil allows the user to easily image the large peripheral vascular system associated with the abdomen, pelvis and lower limbs without moving the patient or the coil.

The Peripheral Vascular coil is designed as a durable item with an expected life of at least 2500 procedures, equivalent to at least five years of service. The specific application of the Peripheral Vascular coil involves MR Imaging at 1.5 Tesla using the GE 1.5T Signa systems with the phased array option.

INTENDED USE:

The Peripheral Vascular Array is a phased array device which operates in the receive-only mode. The device is intended to receive signal from hydrogen protons during MR imaging. The Peripheral Vascular Array, as with any surface coil utilized in MR imaging, is intended to provide improved image quality as a result of the high Signal to Noise ratio (SNR) produced when placing a surface coil close to the anatomy of interest. Higher SNR allows the user to prescribe thinner slices and higher matrices necessary for the high spatial resolution needed in making diagnosis.

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Patient fitness and suitability to undergo an MRI exam utilizing the Peripheral Vascular Array must be determined by the individual physician trained in the field of Diagnostic Magnetic Resonance Imaging.

PERFORMANCE TEST DATA:Signal to Noise Ratio (SNR)

The Medrad 1.5T Peripheral Vascular Array was evaluated using National Electric Manufacturer's Association (NEMA) Standard No. 6, Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images.

Both the Medrad 1.5T Peripheral Vascular Array and the predicate GE 1.5T Body Coil were evaluated with a loaded phantom to determine the SNR for both coils. The coils were evaluated using the same scan parameters to produce identical images. The results were compared to verify the equivalent or increased SNR of the proposed coil.

Image Uniformity Testing:

The Medrad 1.5T Peripheral Vascular Array was evaluated using NEMA Standard MS-6-91 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 the coronal image.

Clinical Testing:

Images were obtained for the proposed Medrad 1.5T Peripheral Vascular Array and the predicate. The GE 1.5T Body Coil results were compared to substantiate improved SNR and morphological detail with the proposed coil.

SAR: Not applicable.

CONCLUSION: Extensive safety, verification, durability, and clinical testing was conducted with the Medrad 1.5T Peripheral Vascular Array 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 1.5T Peripheral Vascular Array will produce the required detailed resolution in surface coil imaging.

end



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1998

Mary Ann Greenwalt, J.D.
Sr. Regulatory Affairs Associate
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051

Re: K974308
Medrad 1.5T Peripheral Vascular Array
Dated: November 14, 1997
Received: November 17, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Greenwalt:

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 requirement, 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/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) : K974308

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INDICATIONS FOR USE:

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(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)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974308