

NOV 3 1998

K982921

510(k) SUMMARY
MEDRAD .5T, 1.0T, 1.5T BREAST 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 Breast Coil

PREDICATE DEVICES: General Electric (GE) Breast Coil

DEVICE DESCRIPTION:

The Medrad Breast Coil is a receive only coil designed to enhance the MR Imaging of the breast anatomy. This coil is designed to be used optimally with either a conventional Signa 1.5T system, or a system including the Phased Array upgrade.

INTENDED USE:

The Medrad Breast 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 breast anatomy.

Anatomical Region:	Breast anatomy
Nuclei Excited:	Hydrogen
Diagnostic Uses:	2D and 3D Imaging

**PROPOSED MEDRAD BREAST COIL
TECHNICAL COMPARISON TO PREDICATE DEVICES:**

The following table compares the predicate GE Breast Coil and the proposed Medrad Breast Coil.

GE Breast Coil (K923025)	Medrad Breast Coil
GE labeling	Medrad labeling
Medrad was responsible for the design and manufacturing of the predicate device, and will remain responsible for the design and manufacturing for the proposed device. The device will be labeled and marketed as "Medrad Product". This is the <u>only</u> change to the device.	

**PROPOSED MEDRAD BREAST
TECHNICAL COMPARISON TO PREDICATE DEVICES(Cont.):**

Patient contacting materials comparison information	
GE Breast Coil	Medrad Breast Coil
Reference K 923025 for material information	All materials used are the same as the GE Breast coil. (Predicate device)
Certification: Medrad, Inc. certifies that the patient contacting materials and formulations for the proposed Medrad Breast 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 Breast coil and the predicate GE Breast Coil.

IMAGE UNIFORMITY - The Medrad Breast 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.

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 Breast Coil.

CLINICAL EVALUATION - Clinical images for the proposed 1.5T Breast Coil have been provided with this submission to demonstrate the clinical effectiveness of the breast coils. Based on these results, and the SNR results for the proposed .5T and 1.0T breast Coils, Medrad concludes that the proposed .5T and 1.0T breast Coils will produce similar clinical image results.

CONCLUSION - Extensive safety, verification, durability and clinical testing was conducted on the predicate GE device. **(K 923025)**. Mechanically and electrically the devices are identical. This labeling change is the only change to the device. The proposed device is deemed by Medrad to be substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982921
Medrad Breast Coil Models M21BRC, M42BRA and M64BRA
Dated: August 18, 1998
Received: August 19, 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 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): K982921

DEVICE NAME: Medrad Breast Coil

INDICATIONS FOR USE:

The Medrad Breast Coil is a receive only coil intended to be used MRI Scanner Systems for imaging of the breast anatomy.

The Medrad Breast 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 X
(Per 21 CFR 801.109)

OR

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

Kimberly A. Symon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982921