

APR 30 1998

510(k) SUMMARY**MEDRAD 1.5T ATD-T**

K974438

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

COMMON/USUAL NAME: MRI System Interface Device

PROPRIETARY NAME: Medrad 1.5T ATD-T

PREDICATE DEVICES: GE 1.5T ATD-III

DEVICE DESCRIPTION:

The Medrad Magnetic Resonance Endorectal Imaging System consists of a disposable, receive only endorectal coil for MR imaging of the male prostate gland and associated anatomy, or other target region of interest, including the cervix and colon. The Medrad ATD-T provides the interface, decoupling, and support functions required to successfully operate the endorectal coils with the GEMS Signa MRI Scanner System with Phased Array capability, and the GEMS Torso Array Coil operating at 1.5 Tesla. The ATD-T consists of two electronic devices, a printed circuit board installed in an Input Port housing attached to the Torso Array Coil posterior cable, and an external unit placed between the Torso Array Coil output cable and the system Phased Array Coil Port. This hardware is intended for repeated use with suitable Medrad disposable MRI Endorectal Coils. The ATD-T sets the tuning and impedance matching of a nominal endorectal coil to the nominal system Larmor frequency, 63.87 MHz for the GEMS Signa 1.5 Tesla MRI System.

The electronic components required to provide effective decoupling disposable endorectal coils resonant response from the MRI RF excitation field during the transmit portion of the MR imaging pulse sequence are included in the ATD-T Input Port Unit.

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The ATD-T External Unit combines the signal from the two posterior coil elements of the Torso Array coil to drive a single Phased Array Coil Port, making one Port available for the output of the endorectal coil. It includes internally selectable circuitry to enable it to be used with either the current version of the GEMS/Gore Torso Array Coil [using PA Ports 3, 4, 5, and 6], or the future version designed to meet IEC-601 First Fault detection conditions [using PA Ports 2, 4, 5, and 7].

The ATD-T is designed as a durable item with an expected life of at least three thousand procedures, equivalent to at least five years of service. The specific application of this version of the ATD-T involves MR imaging at 1.5 Tesla, using a Medrad disposable endorectal coil, and a GEMS Signa 1.5 Tesla MRI System including the GEMS Phased Array feature and the Torso Array Coil.

INTENDED USE:

The purpose of the ATD-T is to provide interface and support functions to allow the use of Medrad disposable endorectal coils with the GEMS Signa 1.5 Tesla MRI Scanner System and Torso Array Coil. The use of the ATD-T is a requirement whenever MR imaging is to be performed using the GEMS Signa 1.5 Tesla MRI System with the Torso Array Coil and any of the Medrad family of disposable endorectal coils. Use of the ATD-T is indicated with all 1.5 Tesla Endorectal Coils.

PERFORMANCE TEST DATA:Signal to Noise Ratio (SNR)

The Medrad 1.5T ATD-T 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 ATD-T and the predicate GE ATD-III 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:

Not Applicable. No uniformity claims are made for this device.

Clinical Testing:

Medrad has demonstrated with Laboratory testing that the proposed Medrad 1.5T ATD-T does not affect the image performance of the Medrad Endorectal Coils, the GE Torso Array, or the GE MRI System. No claims for enhanced images are made herein.

SAR: Not applicable.

CONCLUSION:

Extensive safety, verification, durability, and clinical testing was conducted with the Medrad 1.5T ATD-T to substantiate the claims of the proposed device and to verify that the proposed device is substantially equivalent to the predicate device.



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 .
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Re: K974438
Medrad ATD-T Interface Device
Dated: March 23, 1998
Received: March 24, 1998
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 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

