

JUL - 3 1997

**510(k) SUMMARY**  
**MEDRAD FLEX INTERFACE DEVICE**

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K971380

**OFFICIAL CONTACT:** Rodney J. Rylands  
Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051  
(412) 767-2400 Ext. 3778

**CLASSIFICATION NAME:** Magnetic Resonance Diagnostic Accessory[21  
CFR 892.1000}

**COMMON/USUAL NAME:** Interface Device(Connector)

**PROPRIETARY NAME:** Medrad Flex Interface Device

**PREDICATE DEVICES:** Medrad Probe Interface Device - K926571

**DEVICE DESCRIPTION:**

The Medrad Magnetic Resonance Endorectal Coil Imaging System consists of a disposable, receive only probe for MR Imaging of the associated anatomy. The Medrad Interface Device provides the interface, decoupling, and support functions required to successfully operate the probe with the Siemens Medical Systems Vision & Impact MRI Scanner Systems. The hardware is intended for repeated use with suitable Medrad disposable MRI probes. The Interface Device provides the tuning and impedance matching of the disposable probe to the Siemens Flex Coil Interface optionally used with the Siemens Vision & Impact MRI Systems.

**INTENDED USE:**

The Flex Interface Device is a connecting device between the Siemens MRI System/Siemens Flex Coil Interface and the Medrad Endorectal Imaging Coils. Therefore, this connecting device enables the use of the Medrad Endorectal Coils.

Anatomical Region:	Not Applicable
Nuclei Excited:	Not Applicable
Diagnostic Uses:	Not Applicable



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Rodney J. Rylands  
Regulatory Affairs Coordinator  
Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051-0780

Re: K971380  
Medrad Flex Interface Device  
Dated: April 10, 1997  
Received: April 14, 1997  
Regulatory class: II  
21 CFR 892.1000/Procode: 90 LNH

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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 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): K971380

Device Name: MEDRAD FLEX INTERFACE DEVICE

Indications For Use:

**MEDRAD FLEX INTERFACE DEVICE**  
**(FID 1.5T and FID 1.0T)**  
**FOR SIEMENS MRI SYSTEMS**

**INDICATIONS FOR USE**

The Medrad Flex Interface Device(FID) provides the interface, connection, and support functions to permit the use of Medrad Disposable Endorectal Prostate, Cervix, and Colon Coils, with the Siemens Medical Systems Vision 1.5 Tesla and Impact 1.0 Tesla MRI Scanner Systems.

The Medrad Flex Interface Device and the the Medrad Disposable Endorectal Prostate(BPX), Cervix(BCR), and Colon(PCC) Coils are intended for high resolution Magnetic Resonance Imaging of the human prostate, cervix, colon, and the surrounding pelvic anatomy.

Medrad, Inc.  
One Medrad Drive  
Indianola, PA 15051-0780  
(412) 767-2400

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David A. Johnson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K971380

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

