K982970

OCT 28 1998

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
3234 Ella Lane
New Port Richey, FL 34655

Phone: 813-376-4154
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Contact Person: Ed Ransom or Pat Lamb

Date of Summary: August 28,1998

Trade Name: 3-Way Foley Catheter

Classification Name: Foley Catheter

Predicate Device: ABCO Foley Catheter, K800307

Device Description/ Comparison: Both the device in this submission and the predicate device are used to irrigate and drain the bladder. Both devices use an inflation balloon to retain the Catheter in the bladder. Both devices are 3-way foley Catheters.

Intended Use: This urological catheter is intended for the infusion of sterile solution into the bladder to irrigate, cleanse, or drain the contents of the bladder during surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

MRI Manufacturing and Research, Inc.
c/o·Mr. Ed Ransom
President
Regulatory & Marketing Services, Inc.
3234 Ella Lane
New Port Richey, Florida 34655

Re: K982970
MRI's All Silicone Irrigation 3-way Foley Catheter
Dated: October 12, 1998
Received: October 20, 1998
Regulatory Class: II
21 CFR 876.5130/Procode: 78 EZL

Dear Mr. Ransom:

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): None Assigned At This Time

Device Name: MRI's All Silicone Irrigation 3-Way Foley Catheter

Indications For Use: This urological catheter is intended for the infusion of Sterile solution into the b ladder to irrigate, cleanse, or drain thecontents of the bladder during surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982970/S001

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

(Optional Format 1-2-96)