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K981612

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Rochester® MEDICAL

14.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter and Contact Person: Mary M. Wilen
Rochester Medical Corporation

Name of the Device: Classification Name: Urological Catheter
Common/Usual Name: All Silicone Foley Catheter
Proprietary Name: Rochester Medical Corporation All Silicone Foley Catheter

- Two-Way Foley Catheter
- Three-Way Foley Catheter
- Two-Way Radiopaque Foley Catheter

Predicate Device
The predicate device for purposes of substantial equivalence is the Rochester Medical Corporation All Silicone Foley Catheter which receive marketing approval under K896053, Rüsch Foley Catheters, and Bard Urological Inc. Foley Catheters.

Intended Use of the Device
For urological use only.

Device Description
The catheter consists of a double or triple lumen drainage tube with a single drainage eye on the proximal tip. The three-way catheter has an additional eye for irrigation purposes. The two-way catheter is available with a radiopaque option. The catheter is available in a combination of French sizes, balloon capacities and lengths to accommodate pediatric and adult male and female applications. Available catheter lengths range from 10.6 to 15.8, French sizes from 6 to 26 and balloon sizes 1.5cc to 30cc.

Technological Characteristics
The catheter described in the 510(k) has similar technological and performance characteristics to the predicate devices. The catheter is manufactured entirely from silicone elastomer. The predicate devices are manufactured from silicone elastomer, latex, rubber and red rubber. The device is supplied in French sizes ranging from 6 to 26 and balloon capacities 1.5cc to 30cc. The predicate devices are available in French sizes from 6 to 26 and balloon capacities 1.5cc to 75cc. The device is supplied in pediatric, male and female lengths. The predicate devices are supplied in pediatric, male and female lengths. All of the devices are supplied sterile for single use.

Testing and Results
Test results indicate that the Rochester Medical Corporation All Silicone Foley catheters meet the requirements of ASTM F 623-89 Standard Specifications for Foley Catheters with the exception of requirements 5.3 and 5.5 regarding catheter tip and shaft diameters. These exceptions are due to the proprietary manufacturing process that allows Rochester Medical to manufacture catheters with balloons that are incorporated into the catheter wall rather than being applied during a secondary operation, the tip diameter is equivalent to the balloon diameter which complies with the standard and therefore is not considered clinically significant. Biocompatibility testing was completed on catheter samples including tests for: CCytotoxicity, Systemic Toxicity, Intracutaneous Reactivity, Muscle Implantation with Histopathology, Sensitization and IrIrritation. Results were acceptable for all tests.

One Rochester Medical Drive Stewartville, MN 55976 ISO 9001 CERTIFIED Tel: (507) 533-9600 Fax: (507) 533-9726

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 1998

Ms. Mary M. Wilen
Director of Clinical and Regulatory Affairs
Rochester Medical
One Rochester Medical Drive
Stewartville, Minnesota 55976

Re: K981612
Rochester Medical Corporation All Silicone Foley Catheter
Dated: May 1, 1998
Received: May 6, 1998
Regulatory Class: II
21 CFR 876.5130/Procode: 78 EZL

Dear Ms. Wilen:

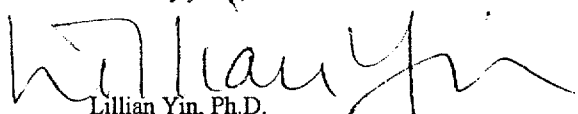
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): _____

Device Name: All Silicone Two-Way Foley Catheter, All Silicone Three-Way Foley Catheter, & Radiopaque Silicone Foley Catheter
Rochester Medical Corporation

Indications for Use:

Two-Way Catheter:
Urethral catheterization for bladder drainage.

Three -Way Catheter:
Urethral catheterization for bladder drainage and bladder irrigation.

Radiopaque Catheter:
Urethral catheterization for bladder drainage with radiopaque substance for radiographic visualization.

INTENDED USE
For urological use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Sathery /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981612

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

(Optional Format 1-2-96)