K033477
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JUN 10 2004

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## 14.0 510(k) SUMMARY

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:** Robert Anglin
Rochester Medical Corporation

**Name of the Device:**
Classification Name: Urological Catheter and Accessories
Proprietary Name: Hydrophilic-Antibacterial Intermittent Catheter
Intermittent Catheter Closed System Kit

**Predicate Devices:**
Rochester Medical Antibacterial Personal®Catheter K001143
Rochester Medical Hydrophilic Personal® Catheter K000723
Mentor Self-Cath Closed System K003873
Hollister InCare Advance Plus Kit K013483
Rusch MMG/O'Neil Catheter K010420

**Intended Use of the Device**

Hydrophilic-Antibacterial Intermittent Catheter
For urological use only. The Hydrophilic-Antibacterial Intermittent Catheter is intended for adult males and females requiring catheterization for management of incontinence, voiding dysfunction and surgical procedures. Efficacy of the Hydrophilic-Antibacterial Intermittent Catheter in preventing urinary tract infection during intermittent use has not been shown. It is not intended as a treatment for active urinary tract infection.
Intermittent Catheter Closed System Kit
For urological use only. The Intermittent Closed System Kit is intended for use by patients for the purpose of bladder drainage.

**Device Description**

The Hydrophilic-Antibacterial Intermittent Catheter consists of a hydrophilic and antibacterial coated single lumen catheter with either two or four drainage eyes on the proximal tip. It is available in male and female lengths and French sizes 12 through 18.

The Intermittent Catheter Closed System Kit consists of a single lumen urethral catheter (Hydrophilic-Antibacterial Intermittent catheter, Personal® Catheter K000723, Hydrophilic Personal® Catheter K000723, or Antibacterial Personal® Catheter K001143) in a closed system drainage bag. The closed system kit provides a no-touch catheter-in-a-bag configuration with an introducer tip and insertion supplies.



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## Technological Characteristics

The catheters described in the 510(k) have similar technological and performance characteristics to the Rochester Medical brand predicate devices (Antibacterial Personal® Catheter K001143 and Hydrophilic Personal® Catheter K000723). All of the catheters are manufactured using similar processes. The catheters are constructed from silicone elastomers and have a hydrophilic and antibacterial coating. The devices are manufactured from the same materials as the predicate devices. The catheters are supplied in the same sizes as the Antibacterial Personal® Catheter, 12 to 18 French male and female lengths. The Intermittent Catheter Closed System Kit is substantially equivalent to the predicate Mentor Self-Cath Closed System, Hollister InCare Advance Plus Kit, and the Rusch MMG/O'Neil Catheter. All of the devices are supplied sterile for single use.

## Testing and Results

The following is a summary of biocompatibility testing that Rochester Medical Corporation has conducted on the Hydrophilic-Antibacterial Intermittent Catheter and the Intermittent Catheter Closed System Kit:

| Test | Conclusion |
|---|---|
| Cytotoxicity Study using the ISO Elution Method | *Test extracts showed a cytotoxic effect. The antibacterial agent is a known mutagen and is known to be cytotoxic. |
| ISO Intracutaneous Study (Saline and Sesame Oil Extracts) | No evidence of significant irritation. |
| USP and ISO Systemic Toxicity Study (Saline and Sesame Oil Extracts) | No mortality or evidence of systemic toxicity. |
| ISO Sensitization Test in Fifteen Guinea Pigs – Maximization Method (Saline and Sesame Oil Extract) | No evidence of delayed dermal contact sensitization. |
| Urinary Bladder Irritation Study with Histopathology | Considered to be a non irritant to the urinary bladder. |
| ISO Muscle Implantation Study -4 Week with Histopathology | The macroscopic reaction was not significant as compared to the negative control material. Microscopically classified as a slight irritant as compared to the negative control article. |

*We conclude that this result is acceptable in the intended clinical application because the drug substance is topically applied and acts locally, is exposed to intact urethra in small doses (total of 2-3 mg during 7 days of use), and has not been shown to be systemically absorbed through the mucous membrane of the urethra.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Mr. Richard Fryar
VP, Research & Development
Rochester® Medical
One Rochester Medical Drive
STEWARTVILLE MN 55976

Re: K033477
Trade/Device Name: Hydrophilic-Antibacterial Intermittent Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 MJC
Dated: May 20, 2004
Received: May 24, 2004

Dear Mr. Fryar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (if Known): **K033477**

DEVICE NAME: Hydrophilic-Antibacterial Intermittent Catheter

INDICATIONS FOR USE:

Urethral catheter for urological use only. The Rochester Medical Corporation Hydrophilic-Antibacterial Intermittent Catheter is intended for urinary bladder drainage in adult males and females requiring catheterization for management of incontinence, voiding dysfunction, and surgical procedures. Efficacy of the Hydrophilic-Antibacterial Intermittent Catheter in preventing urinary tract infection during intermittent use has not been established. The device is not intended to be used as a treatment for active urinary tract infection.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033477

510(k) NUMBER (if Known): **K033477**

DEVICE NAME: Intermittent Catheter Closed System Kit

INDICATIONS FOR USE:

For urological use only. The Intermittent Catheter Closed System Kit is intended for use by patients for the purpose of bladder drainage.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033477