

JUN - 9 1998

K980870

102

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Mr. James R. Whitney
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706

Facsimile: (603) 532-8211

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Urological Catheter

Common Name: Foley Catheter

Proprietary Name: Rüsch Silicone Foley

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Silicone Foley is substantially equivalent to the Bard, Bardex® and Mentor, 4 Sure®, .

4. Description of the Device.

The Rüsch Silicone catheter is of the retention type, commonly called a Foley catheter. The device is a single use, disposable, sterile with retention balloon, which is attached to the silicone shaft. One lumen is for draining fluids to and from the urinary tract. The second lumen is to inflate and deflate the balloon with sterile water. On models with a third lumen, it is used in conjunction with the first lumen for flushing the urinary tract. Sterile water is used for inflation and deflation of the balloon. The distal end has two opposite eye holes, which are used for drainage. On the Tiemann tip there is one hole. Cylindrical, Coude and Tiemann tips are available versions of this product. On the opposing end of the shaft, are a connecting funnel and a Luer activated valve.

Pediatric sizes are available with the same configurations as the adult with the additional feature of a stylet that is inserted prior to the catheter placement. This product is available in sizes 8 Fr to 26 Fr, smooth and profile shafts. Both shafts are available in coated form. Profile shafts provide drainage channels along the shaft length.

5. Intended Use of the Device.

The Rüsç Silicone Foley is used to drain fluids to and from the urinary tract.

6. Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to predicate devices:

The silicone catheter with silicone balloon, ported distal tip, and silicone funnel with and without coating, is equivalent to predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. James R. Whitney
Group Regulatory Affairs Associate
Rusch International
Tall Pines Park
Jaffrey, New Hampshire 03452Re: K980870
Rusch Silicone Foley Catheters
Dated: May 29, 1998
Received: June 1, 1998
Regulatory Class: II
21 CFR §876.5130/Product Code: 78 EZL

Dear Mr. Whitney:

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): _____

Device Name: Rüsch Silicone Foley Catheter

Indications for Use:

The Rüsch Silicone Foley Balloon Catheter is used to drain fluids to and from the urinary tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dobson D. Stalling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980870

Prescription Use 1
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____