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K993063

510(k) Summary

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

Mrs. Julie A. Beaumont
Group Regulatory Affairs Technician
Rüsch Inc.
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6179
E-Mail: jbeaumont@tfx.com

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 Brilliant Silicone Foley

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

The Rüsch Brilliant Silicone Foley is substantially equivalent to the Willy Rüsch AG., Sherwood Medical, Kendall, Baxter, and Bard.

4. **Description of the Device.**

The Rüsch Brilliant Silicone catheter is of the balloon retention type, commonly called a Foley catheter. The device is single use, disposable, and sterile. The central 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 (commonly called a Three-way Catheter), it is used in conjunction with the central lumen for flushing or irrigating the urinary tract.

The distal end has eye holes, which are for drainage. On the opposing end of the shaft, are a connecting funnel (for a drainage bag, purchased separately) and a Luer activated valve.

5. **Intended Use of the Device.**

The Rüsçh Brillant Two Way Silicone Foley is used to drain fluids to and from the urinary tract.
The Rüsçh Brillant Three Way Silicone Foley is used to drain fluids to and from the urinary tract,
and to flush and irrigate 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, distal tip, and inflation/deflation valve is equivalent to predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Julie A. Beaumont
Group Regulatory Affairs Technician
Rüsch International, Inc.
Tall Pines Park
Jaffrey, NH 03452

Re: K993063
Rüsch Brilliant Silicone Foley
Regulatory Class: II
21 CFR 876.5130/Procode: 78 EZL
Dated: August 30, 1999
Received: September 13, 1999

Dear Ms. Beaumont:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device designed to the specifications provided in your 510(k) 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). 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.

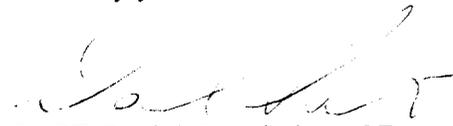
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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" (21CFR 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,



CAPT Daniel G. Schultz, M.D.
Acting 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): K993063

Device Name: Rüsch Brillant Silicone Foley

Indications for Use:

The Rüsch Brillant Two Way Silicone Foley is used to drain fluids to and from the urinary tract.

The Rüsch Brillant Three Way Silicone Foley is used to drain fluids to and from the urinary tract, and to flush and irrigate the urinary tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

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