K971643
Oct. 7, 1997

510 K Summary

[As required by 21 CFR 807.92]

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

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

Telephone: (603) 532-7706

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-BRILLANT Balloon Catheter.

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

The Rüsch-BRILLANT Balloon Catheter is substantially equivalent to the Porgés FOLYSIL Catheter.

4. **Description of the Device.**

The silicon catheter is a balloon retention type, commonly called a Foley catheter. The device is a single use, disposable, sterile, with a retention balloon, which is attached to the silicone two lumen shaft. One lumen is for drainage and the other lumen for inflation and deflation of the balloon. 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 opposing end of the shaft, are a connecting funnel and a luer activated valve.

This product is used with a wire stylet that is inserted prior to catheter placement. This product is available in 6F.

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5. Intended Use of the Device.

The Rüsch-BRILLANT Balloon Catheter is used to drain the 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 hub is equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 1997

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

Re: K971643
Rusch-BRILLANT Balloon Catheter
Dated: August 26, 1997
Received: August 28, 1997
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,

William Yin

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-BRILLANT Balloon Catheter

Indications for Use:

The Rüsch-BRILLANT 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)

Robert R Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971643

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