

JUL 2 1999

K982974

RÜSCH.
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teletex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510 (k) Summary

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

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
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: Ureteral Stent

Common Name: Ureteral Stent

Proprietary Name: Rüsch Ureter Stent Integral Set and Rüsch
Ureter DD Stent Sets

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

The Rüsch Ureter Stent, is substantially equivalent in design, use, and materials to the:

- Microvasive® Boston Scientific Corporation, Mardis Stent Set with guidewire.
- Surgitek®, Cabot Medical Corporation, available with and without guidewire.
- Mentor filiform ureteral double pigtail silicone stent.

- Cook Double Pigtail Standard and AQ Stent Sets
- American Catheter Amcath Uroglide™ Stent
- Microvasive Hydro-Plus™ Coated Marquis Stent

4. Description of the Device.

The Rüsç DD Ureter Stent Set is an over the wire, coaxial, sterile, single use, radiopaque ureter stent that consists of a graduated open or cylindrical tip ureter stent with DD connector, optional hydrogel coating to aid in insertion, an introducer sheath with connector, a PTFE/Hydrogel coated guidewire with flexible core and marking, fixing clamp and an inner pouch that separates the stent from the guidewire during shipping and storage. These items are packaged in a paper and film pouch and sterilized with Ethylene Oxide.

The pouch is printed with company name and address, "Sterile", "Contents sterile provided package is not damaged or open", and the USA caution statement "Caution: Federal law (USA and Canada) restricts this device to sale by or on the order of a physician." The pouches are packed in a paperboard box which bears the manufacturer's name and address and a description of the product within. The box label contains the company name and address, product name, quantity, size, lot number, sterilization date, method of sterilization, expiration date, catalog number, single use statement, Sterile, and length of product.

The Rüsç Integral Ureter Stent Set consists of a ureter stent that is completely radiopaque, coiled cylindrical or open tip with drainage holes at intervals of 5-20 mm, centimeter graduations, optional hydrogel coating, continuous black positioning line to indicate the direction in which the catheter tip coils, and black marking at the catheter end. The introducer sheath is approximately 45 cm long. The spiral stylet is made of stainless steel with optional PTFE/Hydrogel coating and a flexible safety tip and a marked rigid tip and is approximately 100 cm long. There are also plastic clips in the set.

For Ureterorenoscope applications the same features exist but the introducer sheath is approximately 90 cm long and the flexible stylet is approximately 150 cm long. One product configuration allows drainage of the renal system to external collection equipment (not supplied).

5. Intended Use of the Device.

The Rüsçh Ureter Stent is intended for use in temporary internal drainage from the kidney to the bladder or other external collecting location.

6. Summary of Technological Characteristics.

The technological characteristics are the same as or equivalent to predicate devices, which have been listed in section 3.



JUL 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Talls Pines Park
Jaffrey, NH 03452Re: K982974
Rüsch DD Ureteral Stent Set,
Rüsch Integral Ureteral Stent Set
Dated: April 16, 1999
Received: April 19, 1999
Regulatory Class: II
21 CFR §876.4620/Procode: 78 FAD

Dear Ms. Brozowski:

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 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.

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,

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): K98 2974

Device Name: Rüsch Ureter Stent

Indications for Use:

Rüsch ureter stents are intended for use in temporary internal drainage from the kidney to the bladder or other external collecting location.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982974

Prescription Use X

OR

Over-The-Counter Use _____