2/12/99

K983010 1 of 2

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex 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.

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
E-Mail: jrwhitney@compuserve.com

Contact: Same as above

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

Classification Name: Urological Catheter and Accessories

Common Name: Urinary Catheter

Proprietary Name: Self Cath Set

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

The Self Cath Set is substantially equivalent to the Rüsch Catheter for intermittent catheterization.

4. Description of the Device.

The catheter consists of a funnel, a clear tube and a soft, Tiemann tip. The tube has two (2) drainage eyes at the distal end that are opposite and offset. The funnel, at the proximal end, is sized to connect to the drainage bag provided in the kit. For the 'HomeSet', the catheter is packed in an inner plastic bag and a Paper-Film outer pouch.

For the 'Travelset', the catheter is packed in the inner plastic bag and is in the sterile paper-film kit tray with the other contents.

The kit comes in two configurations. One is a 'HomeSet' and the other is a 'Travelset'. Each set comes in men's and woman's configurations which differs by the length of the catheter.

The 'HomeSet' consists of:

(1) 1.5 l drainage catch bag with closure cap
(3) Dab cloths
(3) compression gauze
(1) Tweezers
(1) Table cloth (to set kit contents on)
(1) disposal Bag
(1) cleaning wipe

The 'Travelset' consists of:

(1) Safety Cath
(1) 1.5 l drainage catch bag with closure cap
(2) Dab cloths
(3) compression gauze
(1) Table cloth (to set kit contents on)
(1) Chair Cloth (for under the genital area)
(1) disposal Bag
(2) Rubber gloves
(1) cleaning wipe

Attached to the back of the kit is a bottle of water soluble antiseptic (approx 15 ml).

5. Intended Use of the Device.

The Self Cath is a flexible tubular device to pass fluids to or from the urinary tract. The set is intended to allow for the catheterization of the individual.

6. Summary of Technological Characteristics.

The Self Cath is equivalent in design, use and materials to the predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Miss Karenann Brozowski
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K983010
Self Cath Set/Safety Cath (Urology Drainage Catheter)
Regulatory Class: II
21 CFR 876.5130/Procode: 78 FCM, 78 KOD
Dated: January 12, 1999
Received: January 13, 1999

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your tray. 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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

In addition, we have determined that your device kit contains Povidone Iodine or Benzalkomium Chloride (BZK) which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 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,

for Daniel G. Schultz

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): K983010

Device Name: Self Cath Set

Indications for Use:

The Self Cath is a flexible tubular device to pass fluids to or from the urinary tract. The set is intended to allow for the catheterization of the individual.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983010

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