K974419

JAN 27 1998

Attachment E P1 of 2

Substantial Equivalence 510(k)Summary

Rusch Inc. Simplastic Councill Tip Catheter

To Whom it may concern

Date: November 20, 1997

Submitter/ Contact - Name and Address

Ronald J. Young
Director QA/RA
Rusch Inc.
2450 Meadowbrook Parkway
Duluth, GA 30096

Telephone: (770) 623-0816
Fax: (770) 623-1829

Device Details:

Trade Name: Rusch Inc. Simplastic Councill Tip Catheter

Common Name: Simplastic Councill Tip Catheter

Classification Name: Urological Catheter and Accessories

Predicate Legally Marketed Device: Porges Graham® Catheter

K974419

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Description of Device

The Rusch Inc. Simplastic Councill Tip Catheter may be supplied as a stand alone device or may be accompanied with accessories including a filiform and follower. The Simplastic Councill Tip Catheter consists of a 2-way PVC Foley catheter with a 5 ml balloon and an open tip to fit over a guide. The catheter can be supplied with a lubricious coating to facilitate insertion. The guide will be a flexible PVC shaft with standard threaded male Philips connector for attachment of a detachable filiform. The filiform also consists of a PVC shaft with a standard threaded female Philips connector. The catheter and accessories are supplied sterile. Sterility is by Ethylene Oxide Sterilization.

Device Intended Use

The device design is intended for placement of the Foley catheter in the bladder, for deainage, when there is difficulty in negotiating the urethra.

Technological Characteristics of the Device

The device is equivalent is design and construction to the Porges Graham® Catheter. It comes in a range of sizes from 12 to 26FR.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1998

Ronald J. Young
Director, Quality Assurance
and Regulatory Affairs
RUSCH, Inc.
2450 Meadowbrook Parkway
Duluth, GA 30136

Re: K974419
RUSCH Simplastic Councill Tip Catheter
Dated: December 18, 1997
Received: December 23, 1997
Regulatory Class: II
21 CFR 8876.5130/Procode: 78 EZL

Dear Mr. Young:

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): K974419

Device Name: RUSCH Simplastic Council Tip Catheter

Indications For Use:

The Device is intended for placement of the Foley catheter in the bladder for drainage when there is difficulty in negotiating the urethra

Signed:

Title: Director QA/RA

Date: 1/26/98

(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 K974419

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

(Optional Format 1-2-96)