MAY - 9 2001

Substantial Equivalence 510(K) Summary

Rusch MMG/O'Neil Catheter

To Whom It May Concern:

Date: January 23, 2001

Submitter/Contact Name and Address:

William Slevin
Quality Manager
Rusch Inc.,
2450 Meadowbrook Parkway
Duluth GA 30096

Telephone 770 623 0816
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Details:

Trade Name:

Rusch MMG/O'Neil Catheter

Common Name:

Urinary Catheter

Classification Name:

Urological catheter and accessories Sec. 876.5130 (FCM)

Predicate Legally Marketed Device:

MMG/O'Neil Urinary Catheter K910022

Intended Use:

Urinary Drainage

Description of the Device:

The catheter consists of a tubular PVC or Red Rubber Catheter shaft with attached drainage funnel. The product ranges in sizes from 4Fr to 30Fr. The catheter is designed with Nelaton, Olive, or Tiemann tip. There are two drainage eyes in various configurations. The eyes on the catheter are available as polished or unpolished. The catheter will be available within a closed urine collection bag with a silicone tip, lubrication gel, and a cap. The closed urine collection bag is an extruded plastic film. The funnel on the catheter has an optional color-coding. The kit comes in a range of sizes from 4Fr. to 30Fr.

Technological Characteristics of Device:

This device is equivalent in design, method of manufacture to the MMG/O'Neil Urinary Catheter K910022

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. William Slevin
Quality Manager
Rusch, Inc.
2450 Meadowbrook Pkwy.
DULUTH GA 30096

Re: K010420
Rusch MMG/O'Neil Catheter
Dated: February 5, 2001
Received: February 12, 2001
Regulatory Class: II
21 CFR §876.5130/Procode: 78 FCM and KOD

Dear Mr. Slevin:

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) 594-4639. 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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010420

Device Name: RUSCH MMG/O'NEIL CATHETER

Indications For Use:

ASEPTIC INTERMITTENT SELF CATHETERIZATION

WILLIAM SLEVIN

QUALITY MANAGER

DATE: 02/05/01

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010420

Prescription Use ✓
(Per 21 CFR 801.109)