SEP 2 8 1999

K990500
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II. 510(k) SUMMARY

Submitted by: The Kendall Company
15 Hampshire Street
Mansfield, MA 02048

Contact Person: Paul W. Evans
(508) 261-8203

Date Prepared: January 31, 1999

Proprietary Name: Kendall Ultramer Coude Foley Catheter

Common Name: Coude Foley Catheter

Classification Name: Urological Catheter and accessories (21 CFR §876.5130(b))

Predicate Device: Bardex Lubricath Coude Foley Catheter
510(k) #K910195

Description of the Device:

The Kendall Ultramer Coude Foley Catheter is a sterile, single use urological catheter composed of natural rubber latex with a 5 cc or 30cc balloon and designed with a bent tip to provide transurethral access to an obstructed bladder, for purposes of irrigation and urine drainage. The Coude catheter is exclusively used in the male patient, typically in a hospital setting. The Kendall Ultramer Coude Foley Catheters will be marketed in 12-24 French sizes.

Intended Use of the Device:

The Kendall Coude Foley catheter is a urological catheter designed with a bent tip to provide transurethral access to the obstructed bladder in the male patient for irrigation and urine drainage.

Technological Characteristics:

The Kendall Ultramer Coude Foley Catheter is equivalent to the referenced predicate device in that they are fabricated from similar materials, have the same function, equivalent indications for use, and similar overall design.

Nonclinical testing:

Biocompatibility testing was performed on the Kendall catheter, following ISO-10993 Biological Evaluation of Medical Devices. The testing found that the Materials used in the Kendall Coude Foley Catheter are biocompatible.

Functional/mechanical testing was performed to determine flow rates, balloon integrity, inflated balloon response to traction, balloon volume maintenance, balloon size and shaft size, and deflation reliability. The testing found the Kendall Coude catheter to meet ASTM F623-89 Standard Performance Specifications for Foley Catheters. The testing also verified equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 1999

Mr. Paul W. Evans
Director, Regulatory Affairs
The Kendall Company
15 Hampshire Street
Mansfield, MA 02048

Re: K990500
Kendall Ultramer Coude Foley Catheter
Dated: September 9, 1999
Received: September 10, 1999
Regulatory Class: II
21 CFR §876.5130/Procode: 78 EZL

Dear Mr. Evans:

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

VII. INDICATIONS FOR USE STATEMENT

510(k) Number: K990500

Device Name: Kendall Coude Foley Catheter

Indications for Use: The Kendall Coude Foley Catheter is a urological catheter designed with a bent tip to provide transurethral access to the obstructed bladder in the male patient for irrigation and urine drainage.

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

Concurrence of CDRD, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990500