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EXHIBIT 8

510(k) Summary

NOV - 7 1997

Kendall FAST-CATH Pre-Lubricated Urethral Catheter

In accordance with Section 513(1) of the SMDA and as described in 21 CFR Part 807.3 Final Rule dated December 14, 1994, this Summary is submitted by:

Kendall Healthcare Products Company
15 Hampshire Street
Mansfield, MA 02048

Date: September 15, 1997

1. Contact Person

Paul W. Evans
Manager, Regulatory Affairs
Phone: (508) 261-8203

2. Name of the Device

Classification Name:	Urological Catheter and accessories
Common or Usual Name:	Pre-Lubricated Urethral Catheter
Proprietary Name:	Kendall FAST-CATH Pre-Lubricated Urethral Catheter

3. Statement of Substantial Equivalence

The Kendall FAST-CATH Pre-Lubricated Urethral Catheter is substantially equivalent in intended use, design, and function to the commercially marketed MMG O'Neil Urinary Catheterization System, 510(k) No. K910022, and the Bard Touchless Plus Unisex Pre-Lubricated Urethral Catheter.

4. Description of Device

The Kendall FAST-CATH Pre-Lubricated Urethral Catheter is a sterile, single use system designed for the sterile intermittent catheterization for urine drainage from the bladder. The system is designed for use in both male and female patients.

The system consists of a 1200cc plastic collection bag. A 14 Fr rubber or vinyl urological catheter is self contained within the collection bag. A pre-lubricated introducer tip allows the catheter to be advanced through the top of the collection bag to perform urinary catheterization. A removable cover guards the introducer tip prior to use to maintain sterility.

5. Device Intended Use

The Kendall FAST-CATH Pre-Lubricated Urethral Catheter is intended for sterile intermittent catheterization for urine drainage from the bladder.

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6. Product Comparison

The Kendall FAST-CATH Pre-Lubricated Urethral Catheter is equivalent to the referenced predicate devices in that they are similar in design, fabricated from similar materials, have the same function, and identical indications for use.

7. Nonclinical Testing

Biocompatibility testing was performed on the catheter system following ISO-10993 Biological Evaluation of Medical Devices. This testing found the materials contained no toxic diffusible substances.

Functional testing was performed to determine flow rates, shaft stiffness and other attributes. Testing demonstrated equivalence between the proposed catheter system and commercially available intermittent urological catheterization systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 1997

Mr. Paul W. Evans
Manager, Regulatory Affairs
Kendall Healthcare Product Company
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K973546
Kendall FAST-CATH Pre-Lubricated Urethral Catheter
Dated: September 15, 1997
Received: September 18, 1997
Regulatory class: II
21 CFR §876.5130/Product code: 78 EZD

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 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): K973546

Device Name: Kendall Fast-Cath Pre-Lubricated Urethral Catheter

Indications For Use: Sterile intermittent Catheterization for Urine Drainage from the bladder.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Nathy

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973546

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

(Optional Format 1-2-96)