K024010
Page 1 of 2

JUN 11 2003

510(k) Summary

Kendall ***DOVER Silver*** Hydrogel Coated Silicone Foley Catheter

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Tyco Healthcare/Kendall
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: November 20, 2002

1. Contact Person

David A. Olson
Vice President, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name:	Urological catheter and accessories
Common or Usual Name:	Urinary Drainage Catheter, Silicone Foley

3. Identification of Legally Marketed Device

The proposed Kendall ***DOVER Silver*** Hydrogel Coated Silicone Foley Catheter is substantially equivalent in intended use, function and mode of operation to the ***DOVER*** Silicone Foley Catheter, which was marketed prior to May 28, 1976.

4. Device Description

The Kendall ***DOVER Silver*** Hydrogel Coated Silicone Foley Catheter is a sterile, single patient use, urinary drainage catheter extruded from 100% vulcanized silicone material. It is coated with a lubricious hydrophilic topcoat containing an inorganic silver releasing polymer.

5. Device Intended Use

The proposed device is intended for use in the drainage and/or collection and/or measurement of urine. Generally drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.

Product Comparison

The Kendall ***DOVER Silver*** Hydrogel Coated Silicone Foley Catheter is substantially equivalent to the Kendall **DOVER** Foley Catheter predicate device as each product is intended to pass fluids to or from the urinary tract.

Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Mr. David A. Olson
Vice President, Regulatory Affairs
Tyco Healthcare
15 Hampshire Street
MANSFIELD MA 02048

Re: K024010
Trade/Device Name: Kendall Dover Silver Hydrogel Coated Silicone Foley Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Codes: 78 EZL and KOD
Dated: March 13, 2003
Received: March 14, 2003

Dear Mr. Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). Specifically, your device is substantially equivalent to Kendall DOVER Silicone Foley Catheter. Given that you have not provided any microbial adherence data, you may not make any claims regarding the effectiveness of the inorganic silver ion releasing polymer to reduce microbial adherence to the device or to reduce urinary tract infections in the patients treated with the device. 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx,	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K024010

Device Name:
Kendall Dover Silver Hydrogel Coated Silicone Foley Catheter

Indications for Use:
The proposed device is intended for use in the drainage and/or collection and/or measurement of urine. Generally drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.

Please Do Not Write Below This Line – Continue On Another Page If Needed

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Carolyn Y. Neuland for N. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024010