OCT 6 - 2005

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
14.5Fr Chronic Hemodialysis Catheter with insertion stylets

Section B – 510(K) Summary

Date Summary Was Prepared: June 9, 2005

Submitter's Information:
Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-8461

Contact:
James Welsh
Vice President, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
Telephone: 508-261-8532
Fax: 508-261-6694

Device Trade Name: 14.5 Fr Chronic Hemodialysis Catheter with insertion stylets

Device Common Name: Catheter, Hemodialysis, Apheresis, Intravascular

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
The new configurations of 14.5 Fr Chronic Hemodialysis Catheters are substantially equivalent to the existing Maxid™ and Palindrome™ 14.5 Fr Chronic Hemodialysis Catheters in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of insertion stylets for use during catheter placement.

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
14.5Fr Chronic Hemodialysis Catheter with insertion stylets

Section B – 510(K) Summary

Device Description:

The 14.5 Fr Chronic Hemodialysis Catheter has a radiopaque polyurethane shaft with two large inner lumens designed in a "double D" configuration. The tip of the Maxid catheter is staggered, while the Palindrome is symmetrical. The proximal end of the catheter shaft contains a polyurethane hub assembly and silicone extension sets. The insertion stylets are polyethylene, and extend the full length of the catheter and protrude from the tip. The purpose of the insertion stylet is to provide the clinician with an additional option for catheter placement.

Intended Use:

The 14.5 Fr Chronic Hemodialysis Catheters are intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

Performance Data: Performance data for the insertion stylets of the 14.5 Fr Chronic Hemodialysis Catheters is compared to the design requirements of the predicate devices identified in this 510(K) summary. Results of verification / validation demonstrate that the new catheter/insertion stylet configuration is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2005

Mr. James Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall
15 Hampshire Street
MANSFIELD MA 02048

Re: K051584
Trade/Device Name: 14.5 Fr. Chronic Hemodialysis Catheter with Insertion Stylets
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: September 2, 2005
Received: September 7, 2005

Dear Mr. James Welsh:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit, tray and sport pack (mini kit) have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit, tray and sport pack (mini kit). 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.

In addition, we have determined that your device tray contains lidocaine, 1%, and povidone-iodine swab sticks, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin 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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

510(k) Premarket Notification
14.5Fr Chronic Hemodialysis Catheter with insertion stylets

Appendix 1

Indications for Use Statement

Device Name:

14.5 Fr Chronic Hemodialysis Catheter with Insertion Stylets

Indications for Use:

The 14.5 Fr Chronic Hemodialysis Catheter with Insertion Stylets is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lagman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051584