K041006

MAY 19 2004

Section B – Special 510(k) Summary

Date Summary Was Prepared: April 16, 2004

Submitter's Information:

Kendall
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Contact:

James Welsh
Director, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
Telephone: 508-261-8532
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Device Trade Name: Kendall Tandem-Cath 10Fr Catheter System

Device Common Name: Catheter, Hemodialysis, Apheresis, Intravascular

Classification Panel: Gastroenterology

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
The modified Tandem-Cath 10Fr Catheter System is substantially equivalent to the existing Tandem-Cath 10Fr Catheter System (K002902) in intended use, materials, physical characteristics, and performance characteristics. The modifications attributed to the predicate device are (1) changes to the catheter extrusion process (2) the use of insert molding to attach the polyester cuff in place of adhesive bonding (3) replacement of the original tunneler with a purchased (legally marketed) kit component.

Section B – Special 510(k) Summary (Continued)

Device Description:

The Kendall TANDEM-CATH 10 Fr. Catheter System consists of two 10 Fr. Single lumen catheters. Each catheter is 50 cm long, however, the implant length measured from the cuff to the distal tip differs in arterial and venous catheters. The arterial catheter has an implant length 3 cm shorter than its paired venous catheter. The catheter lumens are distinguished by color-coded printing on the catheter shaft (red-arterial / blue-venous). The catheters are offered with and without side holes. One configuration has 6 side holes oriented in a spiral pattern at the tip of both the arterial and venous catheters. The second configuration has no side holes on either the arterial or venous catheter. The TANDEM-CATH is available in three different implant lengths. These variations are 19 cm / 22 cm (arterial / venous), 23 cm / 26 cm, and 28 cm / 31 cm. The Kendall TANDEM-CATH 10 Fr. Catheter System is supplied in kits that include other accessory devices to be used during the catheter implant process.

A Kendall TANDEM-CATH 10 Fr. Catheter repair kit to replace damaged extensions and / or extension adapters is currently marketed, however as there are no changes made to the repair kit, it is not intended to be within the scope of this special 510k.

Intended Use:

Kendall TANDEM-CATH Catheters are designed for hemodialysis, apheresis, and infusion. They are inserted percutaneously or by cutdown for adult patients. The preferred insertion site is the internal jugular vein.

Performance Data:

Performance data for the modified 10Fr Tandem-Cath is compared to that of the predicate device identified in this 510(k) summary. Results of verification / validation demonstrate that the modified device 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

MAY 19 2004

Mr. James Welsh
Regulatory Affairs Director
The Kendall Company
Tyco Healthcare Group LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K041006
Trade/Device Name: 10 Fr Tandem-Cath Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: April 16, 2004
Received: April 19, 2004

Dear Mr. Welsh:

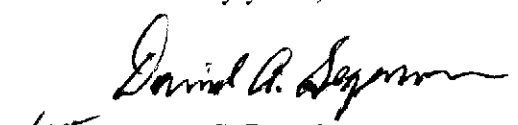
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 (21 CFR Part 807); 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 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. 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/dsma/dsmamain.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

K041006

Indications for Use Statement

Device Name:

10 Fr Tandem-Cath Chronic Hemodialysis Catheter

Indications for Use:

The 10 Fr Tandem-Cath Chronic Hemodialysis Catheter is intended for hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

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. Lagorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041006