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510(k) Summary

Date Summary Was Prepared: 9/8/2010

Submitter's Information: Covidien llc
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DEC 2 2 2010

Contact: Daniel Campion
Manager Regulatory Affairs
Coviden
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Device Trade Name: MAHURKAR™ Triple Lumen Dialysis Catheter

Device Common Name: Catheter, Hemodialysis, Apheresis, Intravascular

Classification Panel: Gastroenterology

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
The MAHURKAR™ Triple Lumen Dialysis Catheter is substantially equivalent to the predicate Mahurkar™ Triple Lumen Dialysis Catheter (K020089) in materials, physical characteristics, and performance characteristics. The expansion of the indications to include Power Injection capabilities through the infusion lumen as well as Central Venous Pressure Monitoring is equivalent to the Bard Power-Trialysis Triple Lumen Dialysis Catheter (K083675).

Device Description:
The MAHURKAR™ Triple Lumen Dialysis Catheter is a 12 Fr radiopaque polyurethane catheter with two large lumens (arterial and venous) and one smaller medial lumen running longitudinally along the length of the catheter shaft. The two large lumens either have curved or straight extensions and the smaller medial lumen have a straight extension. At the distal end of the catheter there is a tapered green, soft radiopaque catheter tip. Each lumen terminates at a separate location along the catheter shaft, designated as the arterial, venous, or medial outlets. The catheter is available in four implantable lengths (13 cm, 16 cm, 20 cm, and 24 cm) with two clear silicone catheters extensions and three internal lumina distinguished by color coded adapters

Intended Use:
The MAHURKAR™ Triple Lumen Dialysis Catheter is intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

Performance Data:
Testing was performed to compare the proposed MAHURKAR™ Triple Lumen Catheter to predicate device. The testing that was performed included Pressure Injection verification testing, including tensile testing and leak and burst testing to ensure catheter mechanical integrity was not diminished after power injections. Additionally Central Venous Pressure testing was conducted to verify that the catheter was capable of being used for accurate pressure monitoring as compared to the predicate device. Results of the

verification / validation testing demonstrate that the modified device is substantially equivalent to the legally marketed predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Daniel Campion
Manager, Regulatory Affairs
Covidien Vascular Therapies, LLC
15 Hampshire Street
MANSFIELD MA 02048

DEC 2 2 2010

Re: K102605
Trade/Device Name: MAHURKAR™ Triple Lumen Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: November 30, 2010
Received: December 8, 2010

Dear Mr. Campion:

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 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/tray 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/tray. 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 and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K102605

Appendix 1
Indications for Use Statement

Device Name:

MAHURKAR™ Triple Lumen Catheter

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Indications for Use:

The MAHURKAR™ Triple Lumen Catheter is intended for short term central venous access for hemodialysis, apheresis, infusion, central venous pressure monitoring and pressure injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K102605