K130725

APR 17 2013

COVIDIEN

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# 510(k) Summary

1. **510(k) Owner:**

Covidien
15 Hampshire Street
Mansfield, MA 02048
Telephone: 508-452-1646
Fax: 508-261-8461

Contact: Dolly Mistry
Title: Senior Regulatory Affairs Associate
Date Prepared: March 14, 2013

2. **Device:**

Trade Name: Argyle™ Polyurethane Umbilical Vessel Catheter
Common Name: Umbilical Vessel Catheter
Classification Name: Intravascular catheter
Regulation Number: 880.5200
Product Code: FOS
Device Class: 2

3. **Predicate Device:**

K850884 – Argyle Polyurethane Umbilical Vessel Catheter*
*The predicate device 510(k), K850884, was submitted by Sherwood Medical Co.; this company was acquired by Covidien, formally Tyco Healthcare/Kendall on October 1, 1998.

4. **Device Description:**

The Argyle™ Polyurethane Umbilical Vessel Catheter is intended for short-term vascular access via umbilical vessels in neonatal patients.

The Argyle Polyurethane Umbilical Vessel Catheter is a single-lumen catheter made of a polyurethane catheter tube which is insert molded to a polypropylene hub. The insertion tip of the catheter has been heat melted to form a smooth, rounded tip to reduce tissue trauma upon insertion.

Encapsulated within the catheter walls are three barium sulfate strips spaced 120° apart, which run the length of the catheter. Placement of the device is facilitated by depth markings, which are printed on the catheter at 1 cm intervals, beginning at 5 cm from the insertion tip and continuing to 25 cm from the tip. Catheter placement must be confirmed by x-ray.

The Argyle Polyurethane Umbilical Vessel Catheter will continue to be available in three sizes: 2.5 Fr.; 3.5 Fr.; and 5 Fr. Each device will continue to be packaged in a Tyvek pouch; 10 pouches are packaged in a carton. The Argyle Polyurethane Umbilical Vessel Catheter does not contain DEHP and is Ethylene Oxide sterilized. The product and packaging is not made of natural rubber latex.

5. **Intended Use:**

The Argyle™ Polyurethane Umbilical Vessel Catheter is intended for short-term vascular access via umbilical vessels in neonatal patients.

6. **Technological Characteristics:**

The modified device has the same fundamental technological characteristics as compared to the predicate device; however, there have been non-fundamental technological changes made to the device since the product clearance in 1985. In April 2011, the Centers for Disease Control and Prevention (CDC) upgraded their recommendation regarding the use of alcohol to minimize contamination risk by scrubbing the access port. As a result, Covidien is modifying the product labeling and the device design to address the changes in clinical practice for the cleaning of access ports of intravascular catheters.

7. **Non-Clinical Performance Data:**

Laboratory testing was completed to support substantial equivalence between the modified device and the current device. The modified device was evaluated to show compliance to the standards requirements as well as performance characteristics related to the modification of the device. The results of the testing show that the modified device continues to meet the requirements of the product specifications and supports the determination of substantial equivalence.

8. **Clinical Data:**

No clinical testing was performed for the determination of substantial equivalence.

9. **Conclusion:**

Based on the nonclinical tests performed on the proposed device, the modified Argyle Polyurethane Umbilical Vessel Catheter is as safe and effective as the legally marketed Argyle Polyurethane Umbilical Vessel Catheter (K850884). The information provided within this 510(k) demonstrates that the modified Argyle Polyurethane Umbilical Vessel Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Ms. Dolly Mistry
Senior Regulatory Affairs Associate
Covidien LP, Formerly Registered As Kendall
15 Hampshire Street
MANSFIELD MA 02048

Re: K130725
Trade/Device Name: Argyle™ Polyurethane Umbilical Vessel Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOS
Dated: March 14, 2013
Received: March 18, 2013

Dear Ms. Mistry:

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). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

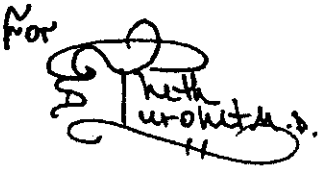
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Argyle™ Polyurethane Umbilical Vessel Catheter

Indications for Use:

The Argyle™ Polyurethane Umbilical Vessel Catheter is intended for short-term vascular access via umbilical vessels in neonatal patients.

Prescription Use_____X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

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