K132567

NOV - 5 2013

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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: August 14, 2013

2. **Device:**

Argyle™ Peripherally Inserted Central Catheter Single Lumen
Trade or proprietary name: The Argyle™ 1.9 Fr Single Lumen Neonatal/Pediatric Peripherally Inserted Central Catheter
Common or usual name: Peripherally Inserted Central Catheter
Device Description: Short-Term Less Than 30 Days, Therapeutic Intravascular Catheter
Regulation Description: Intravascular Catheter
Product Code: FOZ
Regulation Number: 880.5200
Device Class: 2
Predicate Device: K974015 – Argyle® Quick-PICC™ Neonatal/Pediatric Peripherally Inserted Central Catheter and Accessories*
* Please note, the predicate device 510(k) for the Argyle® Quick-PICC™ Neonatal/Pediatric Peripherally Inserted Central Catheter and Accessories, K974015, was submitted by Sherwood Medical Co.; this company was acquired by Covidien, formally Tyco Healthcare/Kendall on October 1, 1998.

Argyle™ Peripherally Inserted Central Catheter Dual Lumen
Trade or proprietary name: The Argyle™ 1.9 Fr Dual Lumen Neonatal/Pediatric Peripherally Inserted Central Catheter
Common or usual name: Peripherally Inserted Central Catheter
Device Description: Long-Term Greater Than 30 Days, Therapeutic Intravascular Catheter
Regulation Description: Percutaneous, implanted, Long-Term Intravascular Catheter
Product Code: LJS
Regulation Number: 880.5970
Device Class: 2
Predicate Device: K042461 and K061936 – Kendall Argyle® 1.9 Fr. Dual Lumen Neonatal/Pediatric Peripherally Inserted Central Catheter

3. **Device Description:**

The Argyle™ Peripherally Inserted Central Catheter is a sterile, single use indwelling catheter inserted into a venous access site for the infusion of fluids, medications and/or nutritional products.

Argyle™ Peripherally Inserted Central Catheter Single Lumen
The Argyle Peripherally Inserted Central Catheter is a single-lumen catheter made of a radiopaque polyurethane catheter tube that is 1.9 Fr. at the distal end. The catheter transitions into a 5 Fr. diameter clear polyurethane tube (pigtail) with an insert molded polypropylene hub through a stabilizing wing junction that is used for attaching the Peripherally Inserted Central Catheter to the patient.

Argyle™ Peripherally Inserted Central Catheter Dual Lumen
The Argyle Peripherally Inserted Central Catheter is a dual-Lumen catheter made of a radiopaque polyurethane catheter tube that is 1.9 Fr. at the distal end. The catheter transitions into two 5 Fr. diameter clear polyurethane tubes (pigtails) with an insert molded polypropylene hub through a stabilizing wing junction that is used for attaching the Peripherally Inserted Central Catheter to the patient. The primary lumen pigtail is longer than the secondary lumen pigtail.

The insertion tip of the Argyle Peripherally Inserted Central Catheter is manufactured in a straight or blunt cut configuration. Placement of the device is facilitated by depth markings, which are printed on the catheter at 1 cm intervals, beginning at 3 cm from the insertion tip and terminating at 30 cm at the proximal end near the stabilizing wing. The 5 cm marks are identified in bold with the 20 cm and 30 cm marks identified with two and three bold marks respectively.

The Argyle Peripherally Inserted Central Catheter will continue to be available in both the single lumen and the dual lumen 1.9 Fr. size. Each device will continue to be packaged in a Tyvek pouch; 10 pouches are packaged in a carton. The Argyle Peripherally Inserted Central Catheter does not contain DEHP and is Ethylene Oxide sterilized. The product and packaging is not made of natural rubber latex.

4. **Intended Use:**

The Argyle™ Peripherally Inserted Central Catheter is designed for cases in which venous catheterization or long term I.V. administration is necessary. Placement is routinely achieved from peripheral venous site, but the catheter may be placed via subclavian cutdown as well. The catheter may be used to administer fluids for hydration and parenteral nutrition, as well as other commonly used intravenous medications.

5. **Technological Characteristics:**

The modified devices have the same fundamental technological characteristics as compared to the predicate devices; however, there have been non-fundamental technological changes made to the devices since the product clearance by the Agency. 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.

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

Laboratory testing was completed to support substantial equivalence between the modified devices and the current devices. The modified devices were evaluated to show compliance to the applicable sections of the standards requirements as well as performance characteristics

related to the modification of the devices. The results of the testing show that the modified devices continue to meet the requirements of the product specifications and support the determination of substantial equivalence.

7. Clinical Data:

No clinical testing was required to be performed for determination of substantial equivalence.

8. Conclusion:

Based on the nonclinical tests performed on the proposed devices, the modified Argyle Peripherally Inserted Central Catheters are as safe and effective as its legally marketed respective predicate devices. The information provided within this 510(k) demonstrates that the modified Argyle Peripherally Inserted Central Catheters are substantially equivalent to the predicate devices.

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

November 5, 2013

Covidien
Dolly Mistry
Senior Regulatory Affairs Associate
15 Hampshire Street
Mansfield, MA 02048

Re: K132567
Trade/Device Name: Argyle Peripherally Inserted Central Catheter Single Lumen and Argyle Peripherally Inserted Central Catheter Dual Lumen
Regulation Number: 21 CFR 880.5970
Regulation Name: Catheter, Intravascular, Therapeutic, Long-Term
Regulatory Class: II
Product Code: LJS/FOZ
Dated: October 10, 2013
Received: October 11, 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 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132567

Device Name:

The Argyle™ Peripherally Inserted Central Catheter Single Lumen

The Argyle™ Peripherally Inserted Central Catheter Dual Lumen

Indications for Use:

The catheter is designed for cases in which venous catheterization or long term I.V. administration is necessary. Placement is routinely achieved from peripheral venous site, but the catheter may be placed via subclavian cutdown as well. The catheter may be used to administer fluids for hydration and parenteral nutrition, as well as other commonly used intravenous medications.

Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C.
Chapman
2013.11.04
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