COVIDIEN

510(K) SUMMARY

JAN 31 2013

1. 510(k) Owner:

Covidien
15 Hampshire Street
Mansfield, MA 02048
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Contact: Jennifer Sullivan
Title: Sr. Regulatory Affairs Specialist
Date Prepared: April 17, 2012

2. Device:

Trade Names: Palindrome™ Precision Symmetric Tip Dual Lumen Catheter
Palindrome™ Precision RT Reverse-Tunneled Catheter
Palindrome™ Precision H Chronic Catheter
Palindrome™ Precision SI Chronic Catheter
Palindrome™ Precision HSI Chronic Catheter
Common Name: Catheter
Classification Name: Implanted Hemodialysis Catheter
Coated Implanted Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Product Code(s): MSD, NYU
Classification: Class III

3. Predicate Devices:

Palindrome™ Symmetric Tip Dual Lumen Catheter	K111372
Palindrome™ RT Reverse-Tunneled Catheter	
Palindrome™ H Chronic Catheter	K112477
Palindrome™ SI Chronic Catheter	
Palindrome™ HSI Chronic Catheter	

4. Device Description:

The Palindrome™ Precision Symmetric Tip Dual Lumen Catheter has a radiopaque shaft with two large D-shaped inner lumens designed in opposing configuration. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the catheter hub which contains suture wings. The distal end of the catheter hub is connected to the double lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical distal tip configuration.

The Palindrome™ Precision RT Reverse-Tunneled Catheter will be supplied with a detached "proximal end" allowing for the catheter tip to be positioned in the vein first before the catheter shaft is pulled through the patient's subcutaneous tunnel tract in a retrograde fashion. The fully assembled Palindrome™ Precision RT Reverse-Tunneled Catheter has a 15.0 Fr. radiopaque shaft with two large D-shaped inner lumens designed in an opposing configuration. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the hub assembly which contains suture wings. The distal end of the catheter hub is connected to the double lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical distal tip configuration.

The Palindrome™ Precision H Chronic Catheter with Heparin coating has a radiopaque polyurethane shaft with two D-shaped inner lumens designed in opposing configuration. The distal end of the catheter extends to a symmetrical tip. The proximal end of the catheter shaft contains a polyurethane hub assembly and silicone extension sets. The catheter contains a heparin coating on its surface from the tip of the catheter to the cuff on the external surface and throughout the entire length on the internal surface (tip to luer adapters). The heparin coating serves to reduce platelet adhesion.

The Palindrome™ Precision SI Chronic Catheter with Silver Impregnated sleeve has a radiopaque polyurethane shaft with two D-shaped inner lumens designed in opposing configuration. The distal end of the catheter extends to a symmetrical tip. The proximal end of the catheter shaft contains a polyurethane hub assembly and silicone extension sets. The catheter contains a silver impregnated sleeve permanently bonded to the outer surface of the device from the hub to the cuff. The silver impregnated sleeve serves to reduce microbial colonization on the external surface of the sleeve which is placed within the subcutaneous tunnel tract.

The Palindrome™ Precision HSI Chronic Catheter with Heparin coating and Silver Impregnated sleeve has a radiopaque polyurethane shaft with two large D-shaped inner lumens designed in opposing configuration. The distal end of the catheter extends to a symmetrical tip. The proximal end of the catheter shaft contains a polyurethane hub assembly and silicone extension sets. The catheter contains a heparin coating on its surface from the tip of the catheter to the cuff on the external surface and throughout the entire length on the internal surface (tip to luer adapters). The heparin coating serves to reduce platelet adhesion. The catheter also contains a silver impregnated sleeve permanently bonded to the outer surface of the device from the hub to the cuff. The silver impregnated sleeve serves to reduce microbial colonization on the external surface of the sleeve which is placed within the subcutaneous tunnel tract.

5. Intended Use:

The uncoated catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral placement.

The Palindrome™ Precision H Chronic Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. The performance of the heparin coating on this catheter in reducing platelet

adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by bench and animal testing.

The Palindrome™ Precision SI Chronic Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days is supported by bench and animal testing.

The Palindrome™ Precision HSI Chronic Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. The performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by bench and animal testing. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days is supported by bench and animal testing.

6. Technological Characteristics:

The modified devices have the same technological characteristics as compared to their respective predicate devices.

7. Performance Data:

The existing Risk Analysis files for the chronic catheter product family were reviewed to identify the clinical risks specifically associated with the modifications related to this pre-market notification. The output of Risk Analysis activities identified the need to conduct additional testing to confirm that the modified chronic catheters continued to meet the relevant acceptance criteria. The test regimen evaluated the devices' performance. Testing included; dynamic flow, static flow, catheter insertion force, thrombogenicity, recirculation, marker band integrity, long term soak, mechanical hemolysis, leachability, tensile, heparin activity, heparin concentration and heparin durability. The results of the performance testing show that the modified devices continue to meet the relevant product specifications.

The results of functional testing and design validation support the determination of substantial equivalence.

8. Conclusion:

Based on non-clinical testing results, Covidien has demonstrated that the modified catheters are substantially equivalent to their respective existing catheters.

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

January 31, 2013

Covidien
% Ms. Jennifer Sullivan
Sr. Regulatory Affairs Specialist
15 Hampshire Street
MANSFIELD MA 02048

Re: K123196
Trade/Device Name: Palindrome™ Precision Symmetric Tip Dual Lumen Catheter
Palindrome™ Precision RT Reverse-Tunneled Catheter
Palindrome™ Precision H Chronic Catheter
Palindrome™ Precision SI Chronic Catheter
Palindrome™ Precision HSI Chronic Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD, NYU
Dated: December 13, 2012
Received: December 14, 2012

Dear Ms. Sullivan:

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K123196

Device Name: Palindrome™ Precision Symmetric Tip Dual Lumen Catheter
Palindrome™ Precision RT Reverse-Tunneled Catheter
Palindrome™ Precision H Chronic Catheter
Palindrome™ Precision SI Chronic Catheter
Palindrome™ Precision HSI Chronic Catheter

Indications for Use:

The Palindrome™ Precision Symmetric Tip Dual Lumen Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral placement.

The Palindrome™ Precision RT Reverse-Tunneled Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral insertion.

The Palindrome™ Precision H Chronic Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. The performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by bench and animal testing.

The Palindrome™ Precision SI Chronic Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days is supported by bench and animal testing.

The Palindrome™ Precision HSI Chronic Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. The performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by bench and animal testing. The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days is supported by bench and animal testing.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123196

Benjamin R. Fisher -S
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