# 510(k) Summary

**Date Summary Was Prepared:** November 1, 2006

NOV - 3 2006

**Submitter's Information:**

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**Device Trade Name:** 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™)

**Device Common Name:** Catheter, Hemodialysis, Implanted, Coated

**Classification Panel:** Gastroenterology

**Legally Marketed Devices to Which Substantial Equivalence is Claimed:**
The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) is substantially equivalent to Kendall's 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating (Palindrome™ Emerald™, K060509) in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of a silver impregnated sleeve to the external surface of the catheter from the hub to the cuff to reduce catheter colonization in the subcutaneous tunnel tract. This silver impregnated sleeve is the same sleeve used on the Kendall 14.5 Fr Chronic Hemodialysis Catheter with Silver Impregnated Sleeve (Palindrome™ Ruby™) cleared for marketing via K060972 on August 4, 2006. K060972 is within the same device classification regulation (876.5540) as the unmodified predicate device, and has the same intended use. No other modifications have been made to either the silver impregnated sleeve or the predicate device, including the heparin coating.

**Device Description:**
The proposed Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) has a radiopaque polyurethane shaft with two large inner lumens designed in a "double D" 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), for the purpose of reduction of platelet adhesion. The proposed catheter also contains a silver impregnated sleeve permanently bound to the outer surface of the device from the hub to the cuff for the purpose of reducing microbial colonization on the external surface of the catheter in the subcutaneous tunnel tract.

**Indications / Intended Use:**
The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) 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 was supported by bench and animal testing.

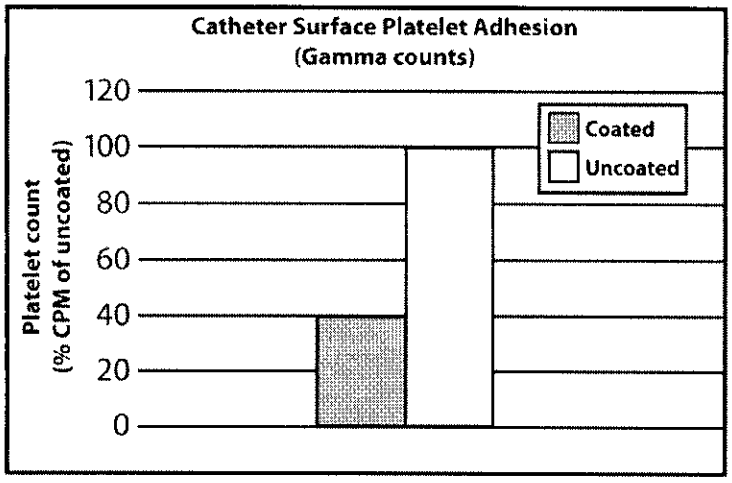
**Performance Data:**
Performance data for the Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) is compared to that of the predicate device identified in this 510(K) summary. Results of verification / validation demonstrate that the modified device is substantially equivalent to the legally marketed device.

**Test Summary:**
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:

- A two hour circulating blood loop test demonstrating a 60% reduction in platelet adhesion on the catheter surface at $p<0.05$.
- A coating durability test, where the catheter was subjected to 720 hours of simulated dialysis conditions and maintained heparin activity levels at twice the minimum activity level required to achieve a 60% reduction in platelet adhesion.
- An *in-vivo* ovine model using six sheep (periodically perfused to simulate dialysis for 24 days) where the reduction in thrombus formation was 82% at $p<0.05$.

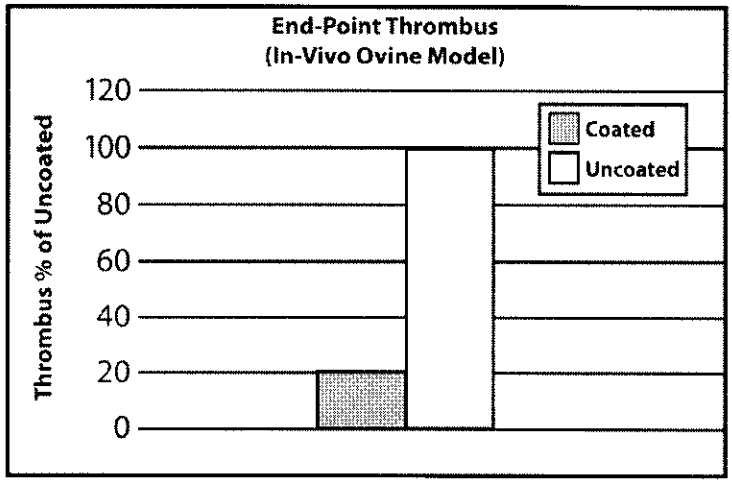
**Test Method Details**:
*In-vitro* evaluations of the coated catheters were performed using a test model which incorporates fresh heparinized bovine blood to assess the relative thromboresistance of the coated catheter as compared to a non-coated catheter. The blood, with radiolabeled autologous platelets, was circulated for 2 hours. Retrieved catheters were visually inspected and then placed in a gamma counter for quantification of platelet adhesion on the catheter surface. The radioactivity data

demonstrates that the coated catheter had 60% less platelets adhered to the surface compared with the uncoated catheter.



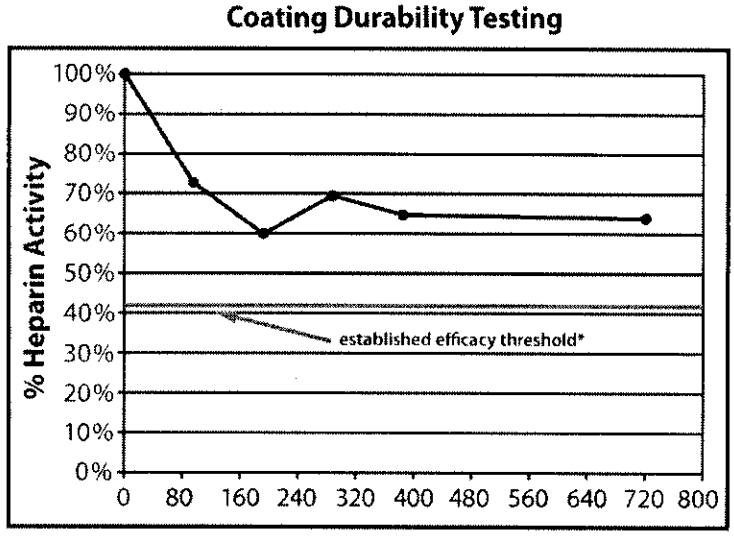

**Total end-point platelet accumulation normalized to the uncoated control.**

*In-vivo* evaluations of the coated catheters were performed using an ovine model. The testing was conducted on 6 sheep with a coated and non-coated catheter implanted into the right and left internal jugular veins of the same sheep. Routine blood perfusion sessions were performed on both catheters to simulate dialysis. Gravimetric analysis performed on the thrombus extracted from the external surfaces of both the coated and non-coated catheters demonstrated an 82% reduction in total thrombus formation after an average of 24 days of implantation as compared to a non-coated catheter.




The durability of the coating was assessed in an *in-vitro* test model that simulates the dynamic flow environment of a dialysis session. The model involves 37°C Saline flowing through the internal surfaces and around the external surfaces of the catheter for a time period that simulates over 12 months of dialysis sessions on the ID of the catheter and over 30 days on the OD of the catheter. The chart below shows that between 60% and 70% of the Palindrome™ Sapphire™ catheter heparin activity remains after 720 hours of continuous flow. This heparin activity is significantly

above the minimum heparin activity established during *in-vitro* blood flow evaluations to achieve a 60% reduction in platelet adhesion.




* The established efficacy threshold was determined in an *in-vitro* circulating bovine blood model using coated catheters with varying levels of heparin activity. The blood, with radiolabeled autologous platelets, was circulated for 2 hours. Platelet counts were quantified for each of the coated catheters with varying heparin activity levels and compared to the uncoated catheter. The results demonstrated that a catheter with 43% of the Palindrome™ Sapphire™ catheter heparin activity still provides a 60% reduction in platelet adhesion on the catheter surface.

**Safety and Effectiveness:**

Testing conducted on the proposed device confirmed that the presence of the silver impregnated sleeve did not affect the safety and catheter performance of the device. In addition to the standard tests applicable to intravascular catheters published by ASTM, ISO, and KDOQI guidelines, testing specific to the silver impregnated sleeve included:

- Biocompatibility testing at highest level of silver loading
- Determination of total silver amount in sleeve to confirm safety versus toxicity and exposure limits
- Silver elution to demonstrate controlled release
- In-vitro studies demonstrating a significant reduction, between 2.1 and 5.5 $\log_{10}$ reductions, in the amount of microbial colonization on the silver impregnated sleeve after repeated challenges with *Staphylococcus aureus*, Coagulase-negative Staphylococcus, *Candida albicans*, and *Escherichia coli* (all clinical isolates).
- In-vivo studies demonstrating a significant reduction, between 2.5 and 4.9 $\log_{10}$ reduction in the amount of microbial colonization on the silver impreganted sleeve after repeated subcutaneous inoculation of *Staphylococcus aureus* (clinical isolate) in a rabbit infection model.

The results of these tests demonstrate that the Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith Martin
Manager, Regulatory Affairs & Scientific Services
Kendall
A Division of TYCO Healthcare Group LP
15 Hampshire Street
MANSFIELD MA 02048

NOV - 3 2006

Re: K062671
Trade/Device Name: Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™), 19cm, 23cm, 28cm and 33cm
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: October 10, 2006
Received: October 11, 2006

Dear Mr. Martin:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062671



# Appendix 1
# Indications for Use

**510(k) Number (if known):** _____

**Device Name:**

Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™)

**Indications for Use:**

The Kendall 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome™ Sapphire™) 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.

Prescription Use ____X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062671