K063441
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Spire Biomedical, Inc., • One Patriots Park • Bedford, MA 01730-2396
TEL (781) 275-6000 • FAX 781 275 6010

SECTION 5 - 510(k) SUMMARY

FEB 1 2 2007

15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter

Date: February 8, 2007

Submitter:
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One Patriots Park
Bedford, MA 01730-2396
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Director of Product Development & Manufacturing
Spire Biomedical, Inc.
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Device Names:

Trade Name: 15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter

Common Name: Catheter, Intravascular, Long-Term

Classification Name: Catheter, Hemodialysis, Implant (Long-Term)
Classification: Class III
Device Code: MSD

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Spire Biomedical, Inc.'s 15.5Fr Decathlon Coated Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (K060155)
- Spire Biomedical, Inc.'s 15.5Fr Alta LR Twin Lumen Fixed Tip Chronic Hemodialysis Catheter (K040509)
- Medtronic Maxima cardiopulmonary bypass circuit (K925626 and K 933586)
- Diametrics Paratrend intravascular blood gas sensor catheter (K970906)
- Cordis Bx Velocity coronary stent (P90043/S024)

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510(k) Summary (Continued)

Device Description:

Spire Biomedical, Inc.'s 15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter is processed with a proprietary Carmeda® BioActive Surface (CBAS®) coating technology that attaches a functionally active heparin to the surfaces of the device. The coating counteracts thrombus from forming on the catheter. Spire's 15.5Fr Alta Gold, Heparin Coated Catheter is fully coated with CBAS® on the internal surface and on the external surface of the catheter body (from 2cm distal to the cuff to the ends of the distal tips; the cuff is not coated).

The coating is essentially non-leaching. Additionally, the maximum amount of heparin on the surface is only 1mg. Therefore; the effects of the entire coating on a patient's coagulation status would be insignificant.

Product Claims:

As demonstrated in an *in-vitro* study, the proprietary End-Point Bonded Heparin Coating attachment mechanism anchors heparin molecules to both internal and external surfaces of the catheter while maintaining heparin's bioactive properties for a minimum of 90 days.[1]

Coating bioactivity was assessed in 90-day durability tests performed on coated catheters in saline. Surface-bound heparin bioactivity (in $pmol/cm^2$) was assessed at each of seven regular intervals. Heparin bioactivity remained essentially constant throughout the test period, demonstrating that the coating's bioactive properties were maintained.

In-vitro studies have demonstrated that the coating reduces total thrombus accumulation by 91% compared to uncoated catheters. The coating was effective in mitigating both disturbed flow-mediated thrombosis (at the catheter tip) and fibrin sheath propagation (on the catheter shaft).[1]

The two-hour *in-vitro* thromboresistance study involved circulation of bovine blood through an outer loop, in which a coated or uncoated catheter was placed. Simultaneously, blood was circulated through the catheter at a constant flow rate. Three criteria were used to determine the effects of the coating in reducing thrombus formation: Pressure increase in the arterial lumen; visual evaluation of the catheters; and end point thrombus accumulation. Results show improved thromboresistance using each of these criteria for Alta Gold Heparin Coated catheters vs. uncoated catheters. End-point thrombus radiolabeled measurements showed an average of 91% reduction in thrombus accumulation for two hours for coated catheters.

[1] Data on file

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Technological Characteristics Comparison to Predicate Devices:

The 15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter is identical to the non-coated Alta catheter (K040509) in physical characteristics, has the same physical characteristics (except for the distal tip configuration), and exact same coating as the Decathlon coated catheter (K060155).

Carmeda® BioActive Surface (CBAS®) coating has been approved for the following legally marketed devices to which substantial equivalence is claimed:

1. Spire Biomedical Decathlon Gold coated catheter (K060155)
2. Medtronic Maxima cardiopulmonary bypass circuit (K925626 and K933586)
3. Diametrics Paratrend intravascular blood gas sensor catheter (K970906)
4. Cordis Bx Velocity coronary stent (P900043/S024)

Performance Data:

A series of physical, mechanical, and biological tests were conducted on the predicate, coated Decathlon catheters (K060155) to demonstrate substantial equivalence to our non-treated Decathlon catheters. With the exception of the in-vitro blood loop test, these tests were not repeated due to the material, outside dimensions, and coating being identical for the Alta Gold catheter. Tests conducted on the Decathlon Gold predicate device are listed below:

- Catheter flows and mechanical properties (tensile strength) including:
  - Catheter to hub
  - Extension to hub
  - Luer adapter to extensions
  - Cuff to catheter
  - Catheter extrusion
  - Catheter flow (bench testing)
- Coating stability and performance claims:
  - Stability testing (leaching) for 90 days
  - Durability testing (bioactivity) for 90 days
  - Durability testing (Accelerated aging for up to 1 year)
- Biocompatibility testing:
  - Tests conducted on the 15.5Fr Decathlon coated catheter demonstrated that this device met the requirements for a permanent contact device per ISO 10993.

The following test was performed on the coated Alta catheters:

- *In-vitro* blood loop testing – 2 Hour study

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shekhar D. Nimkar
Director of Product Development & Manufacturing
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730-2396

FEB 1 2 2007

Re: K063441
Trade/Device Name: 15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: November 2, 2006
Received: November 14, 2006

Dear Mr. Nimkar:

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,

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

Enclosure

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SECTION 4 - INDICATIONS FOR INTENDED USE

510(k) Number: K063441

Device Name: 15.5Fr Alta Gold, Twin Lumen Fixed Tip Coated Chronic Hemodialysis Catheter.

Indications for Use: Spire Biomedical Inc's Alta Gold, Coated Twin Lumen Chronic Hemodialysis Catheter with fixed tips is designed for chronic hemodialysis and apheresis. It is a radiopaque polyurethane with a heparin coating, designed for percutaneous insertion or insertion via cutdown. The ability of the Carmeda End point Bonded Heparin Coating to reduce clotting is supported by in-vitro testing. Catheters longer than 40cm are intended for femoral vein insertion.

Prescription Use √ and/or **Over-the-Counter Use** _____

(Part 21 CFR 801 Subpart D) (Part 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):

David B. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063441