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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

MAY - 9 2006

15.5Fr Decathlon Coated Catheters

Date: January 18, 2006

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
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Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
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Device Names:

Trade Name:	15.5Fr Decathlon Coated Catheters
Common Name:	Catheter, Intravascular, Long-Term
Classification Name:	Catheter, Hemodialysis, Implant (Long-Term)
Classification:	Class III
Device Code:	78 MSD

Device Description:

Spire Biomedical, Inc.'s 15.5Fr Decathlon Coated catheters are 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 Decathlon Coated catheters are fully coated with CBAS® on the internal surface and on 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, maximum amount of heparin on the surface is only 1mg. Therefore, even the effect on a patient's coagulation status would be totally insignificant.

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SECTION 5 - 510(k) SUMMARY (Continued)

PRODUCT CLAIMS:

As demonstrated in two *in-vitro* studies, 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 7 regular intervals. Heparin bioactivity remained essentially constant throughout the test period, demonstrating that the coating's bioactive properties were maintained.

Animal and *in-vitro* studies have demonstrated that the coating reduces total thrombus accumulation by 94% and 96%%, respectively, 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 is circulated through the catheter at a constant flow rate. Three criteria are 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 Decathlon Coated catheters vs. uncoated catheters. End-point thrombus radiolabeled measurements showed an average of 96% reduction in thrombus accumulation for two hours for coated catheters.

One coated and one uncoated catheter was evaluated in each of three animals (ovine). In each, mock dialysis sessions were performed once a week for 1 hour. The catheters were then examined at sacrifice (26-30 days, mean 29 days) using optical and scanning electron microscopy. In each case, the results showed a difference in thrombus accumulation between coated and uncoated Decathlon catheters. Thrombus weight measurements were also performed on two of the animals and showed that the coated Decathlon catheter reduced total thrombus accumulation by 94% when compared with the uncoated Decathlon catheter in the ovine model.

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[1] Data on file

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SECTION 5 - 510(k) SUMMARY (Continued)

Technological Characteristics Comparison to Predicate Devices:

The 15.5Fr Decathlon coated catheter is identical to the non-coated Decathlon catheter in physical characteristics.

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

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

Performance Data:

A series of physical tests were conducted to demonstrate substantial equivalence to our non-treated "Decathlon" catheters including catheter to hub, extension to hub, luer adapter to extensions, cuff to catheter and catheter extrusion.

The following additional tests were conducted on the coated Decathlon catheters to demonstrate coating stability and performance claims:

- Durability testing (bioactivity) for 90 days
- Durability testing (accelerated aging for up to 1 year)
- *In-vitro* blood loop testing 2-hour UAH study
- (3) Animal (ovine) studies (mean duration 29 days)
- Catheter flows (bench testing)
- Mechanical properties (tensile strength)

Biocompatibility testing was conducted on the 15.5Fr Decathlon coated catheter to demonstrate that this device meets the requirements for a permanent contact device per ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Donald D. Fickett, C.Q.E.
Director of RA/QA
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730-2396

MAY - 9 2006

Re: K060155
Trade/Device Name: 15.5 Fr. Decathlon Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (24cm, 28cm, 32cm, 36cm and 40cm)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MSD
Dated: April 12, 2006
Received: April 13, 2006

Dear Mr. Fickett:

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: K060155

Device Name: 15.5Fr Decathlon Coated Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Indications for Use: Spire Biomedical Inc.'s Decathlon Coated Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic Hemodialysis and apheresis. It is a radiopaque polyurethane catheter with a heparin coating, designed for percutaneous insertion or insertion via a cutdown.

The ability of the Carmeda® End-Point Bonded heparin coating to reduce clotting is supported by *in-vitro* and animal testing.

The catheters are offered in 24cm, 28cm, 32cm, 36cm, 40cm and 55cm lengths.

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 R. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060155