



Spire Biomedical, Inc.  
One Patriots Park ♦ Bedford, MA ♦ 01730-2396 ♦ USA  
Tel: (781) 275-6001 ♦ Fax: (781) 275-6010

**510(K) SUMMARY**

**Decathlon Gold Kuhle Twin Lumen Chronic Hemodialysis Catheter**

**Date:** September 25<sup>th</sup>, 2007

**Submitter:** Spire Biomedical, Inc.  
One Patriots Park  
Bedford, MA 01730-2396  
Phone: (781) 275-6000  
Fax: (781) 275-6010

JAN 22 2008

**Contact Person:** Raymond J Kelly IV  
Director of RA/QA  
Spire Biomedical, Inc.  
Phone: (781) 325-0771  
Fax: (781) 275-6010  
E-mail: [rkelly@spirecorp.com](mailto:rkelly@spirecorp.com)

**Device Names:**

*Trade Name:* 15.5Fr Decathlon™ Gold Kuhle Twin Lumen Hemodialysis Catheter with Separated Tips

*Common Name:* Chronic Hemodialysis Catheter

*Classification Name:* Catheter, Hemodialysis, Implanted

**Legally Marketed Device to Which Substantial Equivalence is Claimed:**

Spire Biomedical, Inc.'s (K060155) 15.5Fr Decathlon™ Gold Twin Lumen Hemodialysis Catheter with Separated Tips (Staggered split tip configuration, twin lumen proximal end configuration including identical component clamps, luer adapters, heparin coating, and kit configuration)

**Device Description:** The Decathlon™ Coated Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is constructed of radiopaque medical grade polyurethane. To reduce recirculation during hemodialysis, the arterial lumen of the catheter is shorter than the venous lumen at the catheter's distal end. The catheter has a felt cuff and dual extensions. Each extension has a color coded luer lock adaptor, red for arterial and blue for venous lumen determination. Additionally, each extension has a clamp.



Spire Biomedical, Inc.  
One Patriots Park ♦ Bedford, MA ♦ 01730-2396 ♦ USA  
Tel: (781) 275-6001 ♦ Fax: (781) 275-6010

## 510(K) SUMMARY (CONTINUED)

### Decathlon Gold Kuhle Twin Lumen Chronic Hemodialysis Catheter

**Intended 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. Catheters longer than 40cm are intended for femoral vein insertion.

**Technological Characteristics Comparison to Predicate Device:** The 15.5Fr Decathlon™ Gold Kuhle Twin Lumen Hemodialysis Catheter with Separated Tips is similar to the 15.5Fr Decathlon™ Gold Twin Lumen Hemodialysis Catheter with Separated Tips (K060155). It has the same polyurethane catheter body as the predicate device. The hub-lumen-extension tubes design, luer connections, kit components, packaging and sterilization, and product labeling are identical.

Additionally, the 15.5Fr Decathlon™ Gold Kuhle catheters have identical flow rates and priming volumes as compared to the 15.5Fr Decathlon™ Gold. The identical polyurethane resin is used in both the 15.5Fr Decathlon™ Gold Kuhle and 15.5Fr Decathlon™ Gold.

The only difference between the proposed device and the predicate device is that the device lumens at the distal end of the device diverge at a small angle, whereas the lumens of the predicate device are substantially parallel.

**Performance Data:** Mechanical, physical, and biocompatibility tests were conducted on the predicate device. These tests were not repeated for this submission since this small change (angle between distal end lumens) does not alter any of the characteristics of the catheter. Test data from the predicate device is contained in this application.

**510(K) SUMMARY (CONTINUED)****Decathlon Gold Kuhle Twin Lumen Chronic Hemodialysis Catheter****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.<sup>1</sup>

Coating bioactivity was assessed in 90-day durability tests performed on coated catheters in saline. Surface-bound heparin bioactivity (in pmol/cm<sup>2</sup>) 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).<sup>1</sup>

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.

<sup>1</sup> Data on File.



JAN 22 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Raymond J. Kelly IV  
Director of Regulatory Affairs and Quality Assurance  
Spire Biomedical, Inc.  
One Patriots Park  
BEDFORD MA 01730-2396

Re: K073093

Trade/Device Name: 15.5Fr Decathlon™ Gold Kuhle Twin Lumen Hemodialysis Catheter  
with Separated Tips

Regulation Number: 21 CFR §876.5540

Regulation Name: Blood access device and accessories

Regulatory Class: III

Product Code: MSD

Dated: January 10, 2008

Received: January 11, 2008

Dear Mr. Raymond Kelly:

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 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.

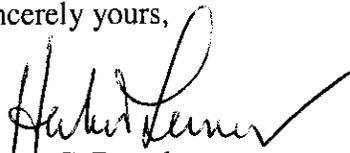
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 and 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 (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh.dsma/dsmamain.html>.

Sincerely yours,



*Nancy C. Brogdon*

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



Spire Biomedical, Inc.  
One Patriots Park ♦ Bedford, MA ♦ 01730-2396 ♦ USA  
Tel: (781) 275-6001 ♦ Fax: (781) 275-6010

**INDICATIONS FOR USE**

510(k) Number (if known): K073093

**Device Name:**

15.5Fr Decathlon™ Gold Kuhle Twin Lumen Hemodialysis Catheter with Separated Tips  
(Lengths: 24cm, 28cm, 32cm, 36cm, 40cm, and 55cm)

**Indications For Use:**

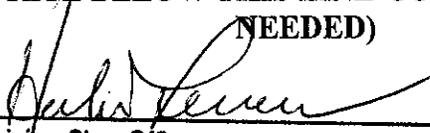
Spire Biomedical, Inc.'s Decathlon Coated Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic Hemodialysis and apheresis. It is a radiopaque polyurethane catheter with a heparin coating, designed for percutaneous insertion or insertion via a cutdown. The ability of the Carmeda® End-Point Bonded heparin coating to reduce clotting is supported by *in-vitro* and animal testing. Catheters longer than 40cm are intended for femoral vein insertion.

Prescription Use ✓  
(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)**



(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices

540(k) Number of CDRH, Office of Device Evaluation (ODE)