K073092

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

510(K) SUMMARY

JAN 29 2008

Decathlon Kuhle Twin Lumen Chronic Hemodialysis Catheter

Date: September 25th, 2007

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
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Contact Person:
Raymond J Kelly IV
Director of RA/QA
Spire Biomedical, Inc.
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Device Names:

Trade Name: 15.5Fr Decathlon™ 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 (K032061, K042858) 15.5Fr Decathlon™ Twin Lumen Hemodialysis Catheter with Separated Tips (Staggered split tip configuration, twin lumen proximal end configuration including identical component clamps, luer adapters, and kit configuration)

Device Description: The Decathlon™ 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.

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510(K) SUMMARY (CONTINUED)

Decathlon Kuhle Twin Lumen Chronic Hemodialysis Catheter

Intended Use: Spire Biomedical, Inc.'s Decathlon Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic hemodialysis and apheresis. It is a radiopaque polyurethane catheter designed for percutaneous insertion or insertion via cutdown. Catheters longer than 40cm are intended for femoral vein insertion.

Technological Characteristics Comparison to Predicate Device: The 15.5Fr Decathlon™ Kuhle Twin Lumen Hemodialysis Catheter with Separated Tips is similar to the 15.5Fr Decathlon™ Twin Lumen Hemodialysis Catheter with Separated Tips (K032061, K042858). 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™ Kuhle catheters have identical flow rates and priming volumes as compared to the 15.5Fr Decathlon™. The identical polyurethane resin is used in both the 15.5Fr Decathlon™ Kuhle and 15.5Fr Decathlon™.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2008

Mr. Raymond Kelly
Director of Regulatory Affairs & Quality Assurance
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730

Re: K073092
Trade/Device Name: 15.5Fr. Decathlon™ Kuhle Twin Lumen Hemodialysis Catheter with Separated Tips; (Lengths: 24-, 28-, 32-, 36-, 40-, and 55cm)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 11, 2008
Received: January 14, 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,

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

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INDICATIONS FOR USE

510(k) Number (if known): K073092

Device Name:

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

Indications For Use:

Spire Biomedical, Inc.'s Decathlon™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic hemodialysis and apheresis. It is a radiopaque polyurethane catheter designed for percutaneous insertion or insertion via cutdown. 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
510(k) Number K073092

Concurrence of CDRH, Office of Device Evaluation (ODE)