K032061 Page 1 of 2

Spire Biomedical, Inc. • One Patriots Park • Bedford, MA 01730-2396
(781) 275-6001 • (781) 275-6010 fax

DEC 2 3 2003

SECTION 7

510(K) SUMMARY

15.5Fr Polyurethane "Decathlon" Twin Lumen Chronic Hemodialysis Catheter

Date: July 2, 2003

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
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Contact Person:
Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
Phone: (781) 275-6001 x221
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Device Names:

Trade Name: 15.5Fr "Decathlon" Twin Lumen Chronic Hemodialysis Catheters

Common Name: Catheter, Intravascular, Long-Term

Classification Name: Catheter, Hemodialysis, Implant (Long-Term)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Spire Biomedical, Inc.'s Pourchez XpressO™ (Split tip distal end, twin lumen proximal end configuration including identical component clamps, luer adapters, product performance and same indication for use)
2) Medical Components, Inc. Ash Split Cath™ (round outer profile with semi-circular cross-sectional lumens)
3) Kendall Healthcare Maxid™ (same polyurethane material for catheter body, hub and tubing)

Device Description: The 15.5Fr "Decathlon" Twin Lumen Chronic Hemodialysis Catheter is a product line extension of Spire Biomedical, Inc.'s Pourchez XpressO™ flexible radiopaque silicone catheters and supplements our Pourchez XpressO catheter line by offering a polyurethane catheter with similar tip-to-hub length catheters of 24cm, 28cm, 32cm, 36cm & 40cm.

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510(K) Summary (Continued)

15.5Fr Polyurethane "Decathlon" Twin Lumen Chronic Hemodialysis Catheter

Intended Use: The indications for use of the 15.5Fr "Decathlon" catheters are identical to the Pourchez XpressO™ Twin Lumen Chronic Hemodialysis catheter with Separated Tips. The 15.5Fr "Decathlon" is designed for chronic (long-term) hemodialysis and apheresis. It is designed for percutaneous insertion or insertion via cutdown into the jugular or subclavian vein.

Technological Characteristics Comparison to Predicate Devices: The 15.5Fr "Decathlon" Twin Lumen Chronic Hemodialysis Catheter's split tip design (with the exception of the polyurethane catheter body, clear urethane tubing, urethane hub and cross-sectional profile) are identical to our silicone Pourchez XpressO™ catheters listed within our 510(K) Premarket Notification Submission (K013160). The round outer profile with semi-circular cross-sectional lumens is similar to the MedComp Ash Split Cath™. The polyurethane catheter body material is identical to that used in the Kendall Healthcare Maxid™ catheter, as verified by an IR Scan analysis (**Appendix G**). Optional use of polyvinyl chloride luer adapters has also been qualified.

Selected biocompatibility testing was conducted on the catheter and carbothane resin. Results are provided in **Appendix B**.

Performance Data: 15.5Fr "Decathlon" catheters have similar product performance flow rates and priming volumes as compared to our silicone Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheters with Separated Tips. The polyurethane resin is similar to the Kendall Maxid catheter. A series of mechanical and physical tests were performed to demonstrate substantial equivalence to predicate devices or conformation to established ISO standards for hemodialysis catheters. In all cases, the 15.5Fr "Decathlon" catheter demonstrated equivalent or better performance to the predicate devices and/or exceeded the minimum acceptance criteria established by the appropriate standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2003

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

Re: K032061
Trade/Device Name: 15.5Fr Polyurethane "Decathlon" Twin Lumen Chronic Hemodialysis Catheter; 24cm, 28cm, 32cm, 36cm and 40cm
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: September 29, 2003
Received: October 6, 2003

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.

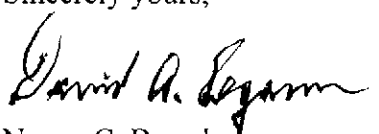
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (301) 594-4616. 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/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

Enclosure

K032061

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APPENDIX B – Indications for Use Statement

Device Name: 15.5 Fr. Decathlon Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (24cm, 28cm, 32cm, 36cm & 40cm)

Indications for Use: The 15.5Fr. Decathlon Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic (long-term) hemodialysis and apheresis. It is designed for percutaneous insertion or insertion via cutdown.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032061

Prescription Use ✓