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Spire Biomedical, Inc. • One Patriots Park • Bedford, MA 01730-2396
(781) 275-6001 • (781) 275-7470 fax

510(K) Summary

24cm Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Date: May 16, 2002

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
Phone: (781) 275-6000
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Contact Person:
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Director of RA/QA
Spire Biomedical, Inc.
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Device Names:

Trade Name: 24cm Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Common Name: Catheter, Intravascular, Long-Term

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

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Medical Components, Inc. Ash Split Cath™ (Flow Performance Characteristics)
2) Spire Biomedical, Inc. Pourchez XpressO™ (Performance and Materials Compatibility)

Device Description: The 24cm tip to hub length Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is a product line extension of Spire Biomedical, Inc.'s the Pourchez XpressO™ flexible radiopaque silicone catheters. The 24cm catheter supplements the other four tip to hub length catheters (28cm, 32cm, 36cm and 40cm) catheters. The 24cm is also available with and without side holes on the distal ends.

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510(K) Summary (Continued)

24cm Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Intended Use: The indicated use and indications of the Pourchez XpressO™ catheter have not changed. It 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.

The 24cm tip to hub length Pourchez XpressO™ Catheter is a product line extension.

Technological Characteristics Comparison to Predicate Devices: The 24cm Pourchez XpressO™ Catheter has the same intended use, same number of lumens, similar cross-sectional lumen area, and the same insertion method and insertion sites as the other tip to hub length Pourchez XpressO™ catheters. The 24cm Pourchez XpressO™ Catheter consists of the identical materials of construction as the Pourchez XpressO™ catheters listed within our initial 510(K) Premarket Notification Submission (K013160).

Additionally, the 24cm Pourchez XpressO™ catheter has similar flow rates and priming volumes as the MedComp Ash Split Cath™.

Performance Data: A series of tests were performed to demonstrate substantial equivalence to predicate devices or conformation to established ISO standards for hemodialysis catheters. In all cases, the 24cm Pourchez XpressO™ catheter demonstrated equivalent or superior performance to the predicate devices 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

MAY 17 2002

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

Re: K021212
Trade/Device Name: 24cm Pourchez XpressO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (with and without side holes)
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: April 12, 2002
Received: April 17, 2002

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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, 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.

In addition, we have determined that your device kit contains Licocaine 1% which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act, may be obtained 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/dsma/dsmamain.html

Sincerely yours,

David A. Segerson for

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

Enclosure

K021212

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APPENDIX A – INDICATIONS FOR USE STATEMENT

Device Name: The 24cm Pourchez XpressO™ Silicone Twin Lumen Catheter with Separated Tips

Indications for Use: The Pourchez XpressO™ is a silicone twin lumen catheter with separated tips designed for chronic (long-term) hemodialysis and apheresis. It is designed for percutaneous insertion or insertion via cutdown.

Prescription Use ✓
(Per 21 CFR 801.109)

Division Sign-Off
Division of Reproductive, Abdominal
Radiological Devices
510(k) Number K021212