K041559 page 1 of 2

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

JUL 3 0 2004

Section 7
510(k) Summary
55cm Pourchez RetrO

Date: June 7, 2004

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

Contact Person:
Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
Phone: (781) 275-6001 x221
Fax: (781) 275-6010
e-mail: dfickett@spirecorp.com

Device Names:

Trade Name: 55cm Pourchez RetrO Kit

Common Name: Long Term Hemodialysis catheter

Classification Name: Chronic Hemodialysis Catheter

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Spire Biomedical, Inc. Pourchez RetrO Twin Lumen Silicone Chronic Hemodialysis Catheter with Separated Tips "K022000."

Device Description: 55cm Pourchez RetrO™ Silicone Twin Lumen Chronic Hemodialysis Catheter with Separated Tips.

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

510(k) Summary (Continued)

55cm Pourchez RetrO Catheter Kit

Intended Use: The 55cm Pourchez RetrO 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.

Catheters longer than 40cm can be used for femoral insertion.

Technological Characteristics Comparison to Predicate Devices: The 55cm Pourchez RetrO catheter uses the exact same materials of construction.

Performance Data: A series of mechanical and physical tests, including tensile and flow, were performed to demonstrate substantial equivalence to predicate devices or conformation to established ISO standards for hemodialysis catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2004

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

Re: K041559
Trade/Device Name: Pourchez RetrO Twin Lumen Chronic Hemodialysis Catheter with Separated Tips
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: June 7, 2004
Received: June 10, 2004

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,

Nancy C Brogdon

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

Enclosure

K041559 page 1 of 1

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

APPENDIX B – Indications for Use Statement

Device Name: Pourchez RetrO Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Indications for Use: The 55cm Pourchez RetrO 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.

Catheters longer than 40cm can be used for femoral vein insertion.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041559

Prescription Use ✓
(Per 21 CFR 801.109)