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

Section 7
510(k) Summary
Pourchez RetrO Repair Kit

NOV 6 2002

Date: November 5, 2002

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.
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Device Names:

Trade Name: Pourchez RetrO Repair Kit

Common Name: Repair Kit

Classification Name: Kit, Repair Catheter, Hemodialysis

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Spire Biomedical, Inc. Pourchez RetrO Twin Lumen Silicone Chronic Hemodialysis Catheter with Separated Tips (extension adapters only) "K022000."
2) Kendall Tandem-Cath™ (in design and intended use) "K002900"
3) Bard Access Systems, Inc. Catheter Repair Kit with Replacement connector (in intended use) "K011015"

Device Description: Pourchez RetrO™ Repair Kit is designed to replace worn or damaged extension connector adapters on Spire Biomedical, Inc.'s Pourchez RetrO Twin Lumen Silicone Hemodialysis Catheters with Separated Tips.

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510(k) Summary (Continued)

Pourchez RetrO Repair Kit

Intended Use: The Pourchez RetrO Repair Kit is designed to replace worn or damaged Pourchez RetrO extension adapters.

Technological Characteristics Comparison to Predicate Devices: The Pourchez RetrO Repair Kit uses the same materials of constructions as those of the original extension adapters supplied with the Pourchez RetrO catheters.

Performance Data: A series of tensile tests were performed to demonstrate substantial equivalence to predicate devices or conformation to established ISO standards for hemodialysis catheters. In all cases, the Pourchez RetrO Repair Kit extension adapters exceed the minimum tensile strength required by ISO 10555-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 6 2002

Re: K022644
Trade/Device Name: Pourchez RetrO™ Repair Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NFK
Dated: August 7, 2002
Received: August 8, 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 (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 (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/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

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APPENDIX B – Indications for Use Statement

Device Name: Pourchez RetrO Repair Kit

Indications for Use: Pourchez RetrO™ Repair Kit is designed to replace worn or damaged extension connector adapters on Spire Biomedical, Inc.'s Pourchez RetrO catheters.

(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)

Prescription Use ✓
(Per 21 CFR 801.109)

[redacted]
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022644