



• One Patriots Park • Bedford, MA 01730-2396 SEP - 1 2006
 TEL: (781) 275-6000 • (781) 275-6010 fax

SECTION 5 - 510(k) SUMMARY

RetrO Silver™ and XpressO Silver™ Coated Twin Lumen Chronic Hemodialysis Catheters with Separated Tips

Date: February 2, 2006

Submitter:

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

Contact Person:

Ray Kelly
 Director of RA/QA
 Spire Biomedical, Inc.
 TEL: (781) 275-6001 x370 FAX: 781 275 6010
 email: rkelly@spirecorp.com

Device Name(s):

Trade Names: RetrO Silver™, XpressO Silver™
 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® Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (K013160 & K021212).
2. Spire Biomedical, Inc.'s Pourchez RetrO® Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (K022000 & K041559).
3. Electro-Biology, Inc.'s X Fix™ Dynafix™ System – SC Bone Screws with silver coating (K961433).
4. Arrow International, Inc., Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter (K993933)

Device Description: Spire Biomedical, Inc.'s RetrO Silver™ and XpressO Silver™ are radiopaque silicone catheters that have been coated with silver using a physical vapor deposition process. The silver is applied to the distal end of the catheter from approximately 2-5mm below the cuff to the tips, and is on the exterior surfaces of the catheter only. Aside from the silver coating, the catheters have identical physical characteristics to the non-coated RetrO and XpressO catheters, both of which have 510(k) Premarket Approval. The catheter configurations (available lengths and insertion kit components) are also identical.



Spire Biomedical Inc. • One Patriots Park • Bedford, MA 01730-2396
 TEL: (781) 275-6000 • (781) 275-6010 fax

SECTION 5 - 510(k) SUMMARY (Continued)

The silver coating is applied by a vacuum-based physical vapor deposition process called ion beam assisted deposition (IBAD). IBAD combines evaporation with concurrent ion beam bombardment. The process is performed under a high vacuum environment. A silver vapor is formed via electron beam evaporation and deposited onto the catheter. Simultaneously, energetic ions bombard the catheter surface and coating as it is deposited. The coating consists of three layers: titanium, palladium, and silver. The film layers are deposited sequentially with the titanium and palladium layers being completely covered by the silver.

Product Claims:

The silver coating on the catheter may reduce bacterial surface colonization for up to two months. This performance was supported by literature citing clinical testing.¹

The silver coating also reduces friction, facilitating insertion through the sheath. Silver coated catheters were evaluated for frictional resistance when passed through the peel-away sheath. For this evaluation, coated and uncoated catheters were placed into the sheath, which was fixed in a horizontal position on a test rig platform. A load was applied to the outside of the sheath, and force was then applied incrementally to the catheter until it started to slide in the sheath. Friction was calculated from the ratio of the force required to move the catheter to the normal force applied to the sheath. Tests were conducted at several different normal load conditions. All measurements were conducted in the dry state. On average, the coated catheter provided a 65% reduction in friction against the sheath.

The long-lasting silver coating exhibits extremely low silver elution rates, based on saline immersion studies. For these tests, segments were cut from the shafts of silver coated catheters and placed into polypropylene centrifuge tubes filled with Mammalian Ringer's solution. The tubes were placed in an incubator and maintained at a constant temperature (35-37°C); they were agitated at least five times per week during the test. At the end of the test period, the catheter samples were removed, and the amount of silver in the solution measured. Tests were performed in triplicate for periods ranging from 1 day to 8 weeks. There was a small rise in silver concentration during the first day, after which the silver elution exhibited essentially linear behavior. After 60 days, approximately 0.2% of the total silver on the catheter segment had been released into solution.

Indications for Use: Spire Biomedical Inc.'s RetrO Silver™ and XpressO Silver™ Coated Twin Lumen Chronic Hemodialysis Catheters with Separated Tips are designed for chronic hemodialysis and apheresis. They are radiopaque silicone catheters designed for percutaneous insertion or insertion via a cutdown. Catheters longer than 40cm are intended for femoral vein insertion.

The silver coating on the catheter may reduce bacterial surface colonization for up to two months. This performance was supported by literature citing clinical testing.¹

1. Bambauer R, Mestres P, Schiel R, Schneidewind-Muller JM, Bambauer S, Sioshansi P. Large bore catheters with surface treatments versus untreated catheters for blood access. *Journal of Vascular Access* 2001;2:97-105.



One Patriots Park • Bedford, MA 01730-2396
TEL: (781) 275-6000 • (781) 275-6010 fax

510(k) SUMMARY (CONTINUED)

Technological Characteristics Comparison to Predicate Devices:

1. The silver coated RetrO Silver™ catheters have the same intended use, sizes, number of lumens, cross-sectional lumen area, insertion method, and insertion sites as the predicate Pourchez RetrO catheters. Physical characteristics are essentially identical to non-coated RetrO catheters.
2. The silver coated XpressO Silver™ catheters have the same intended use, sizes, number of lumens, cross-sectional lumen area, insertion method, and insertion sites as the predicate Pourchez XpressO catheters. Physical characteristics are essentially identical to non-coated XpressO catheters.
3. The silver coating is the same as that applied to Electro-Biology, Inc.'s X Fix™ Dynafix™ System – SC Bone Screws.
4. Arrow International, Inc.'s, Two-Lumen Hemodialysis Catheterization Kit with Blue FlexTip® ARROWg+ard Blue® Catheter contains a silver-based coating on the surface.

Performance Data: A series of tests was performed to demonstrate substantial equivalence to the predicate RetrO and XpressO catheters. The RetrO Silver™ and XpressO Silver™ catheters have demonstrated equivalent flows and mechanical properties compared to the predicate devices. Biocompatibility testing has been performed on the coated catheters. Elution testing has been performed and results compared to Arrow International, Inc.'s ARROWg+ard Blue® Catheter predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP - 1 2006

Re: K060288

Trade/Device Name: RetrO Silver™ and XpressO Silver™ Coated Twin Lumen Chronic Hemodialysis Catheters with Separated Tips

Regulation Number: 21 CFR §876.5540

Regulation Name: Blood access device and accessories

Regulatory Class: III

Product Code: MSD

Dated: August 9, 2006

Received: August 10, 2006

Dear Mr. 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 (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 (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 (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure



Spire Biomedical, Inc. • One Patriots Park • Bedford, MA 01730-2396
TEL: (781) 275-6000 • (781) 275-6010 fax

SECTION 4 - INDICATIONS FOR USE

510(k) Number (if known): K060288

Device Name(s): RetrO Silver™ and XpressO Silver™ Coated Twin Lumen Chronic Hemodialysis Catheters with Separated Tips

Indications for Use: Spire Biomedical Inc.'s RetrO Silver™ and XpressO Silver™ Coated Twin Lumen Chronic Hemodialysis Catheters with Separated Tips are designed for chronic hemodialysis and apheresis. They are radiopaque silicone catheters designed for percutaneous insertion or insertion via a cutdown. Catheters longer than 40cm are intended for femoral vein insertion.

The silver coating on the catheter may reduce bacterial surface colonization for up to two months. This performance was supported by literature citing clinical testing.¹

1. Bambauer R, Mestres P, Schiel R, Schneidewind-Muller JM, Bambauer S, Sioshansi P. Large bore catheters with surface treatments versus untreated catheters for blood access. Journal of Vascular Access 2001;2:97-105.

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060288