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

DEC - 5 2006

SECTION 5 - 510(k) SUMMARY

Repair Kit for XpressO®, Decathlon™, and Alta LR™ Catheters

Date: August 15, 2006

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
Phone: (781) 275-6000
Fax: (781) 275-6010

Contact Person:
Shekhar Nimkar
Director of Product Development & Manufacturing
Spire Biomedical, Inc.
TEL: (781) 275-6001 x203
FAX: (781) 275-6010
email: snimkar@spirecorp.com

Device Name:

Trade Name:	Repair Kit for Xpresso®, Decathlon™, & Alta LR™ Catheters
Common Name:	Catheter Repair Kit
Classification Name:	Repair Kit, Catheter, Hemodialysis
Classification:	Class II
Device Code:	78 NFK

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DEVICE DESCRIPTION:

The Spire BioMedical repair kit is used to replace damaged female luer connectors, clamps, or repair extensions where there is a minimum of 2.5 cm viable extension tubing. This repair kit is to be used on the Spire BioMedical Xpresso®, Decathlon™, and Alta LR™ catheters.

PRODUCT CLAIMS:

Repair kit for damaged female luers, clamps, and extension where there is a minimum of 2.5 cm of viable extension.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TO PREDICATE DEVICES:

The Spire BioMedical repair kit for Xpresso®, Decathlon™, and Alta LR™ catheters is similar to the Pourchez Retro Repair Kit (K022644) in physical characteristics and materials.

PERFORMANCE DATA:

A series of physical tests were conducted to demonstrate substantial equivalence to the Pourchez Retro Repair Kit (K022644). Refer to Section 18 "Bench Testing" for physical test data.

Biocompatibility testing was conducted only on the new materials. A comparison table for the materials is provided in Section 11.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Shekhar D. Nimkar
Director of Product Development & Manufacturing
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730-2396

DEC - 5 2006

Re: K062435
Trade/Device Name: Repair Kit for XpressO®, Decathlon™, & Alta LR™ Catheters
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NFK
Dated: November 28, 2006
Received: November 30, 2006

Dear Mr. Nimkar:

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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 (Premarket Approval), it may be subject to such 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.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K062435

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SECTION 4 - INDICATIONS FOR INTENDED USE

510(k) Number: K062435

Device Name: Repair Kit for Xpresso®, Decathlon™, & Alta LR™ Catheters

Indications for Use: To replace damaged female luer connectors, clamps, or repair extensions where there is a minimum of 2.5 cm viable extension tubing.

Repairs Spire BioMedical Xpresso®, Decathlon™, & Alta LR™ catheters.

Prescription Use √ ~~and~~/or **Over-the-Counter Use** _____

(Part 21 CFR 801 Subpart D) (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 K062435