K070177
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Fresenius Medical Care

MAR 29 2007

Fresenius Naturalyte® Liquid Acid Concentrates "Special" 510(k) Premarket Notification

Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Name:	Fresenius Medical Care North America
Address:	920 Winter Street Waltham, MA 02451
Phone:	(781)-699-4475
Fax:	(781) 699-9635
Contact Person:	Janet C. Kay, Manager Regulatory Affairs
Date of Preparation:	16 January, 2007

B. Device Name:

Trade Name:	Naturalyte Liquid Acid Concentrate
Common/Usual Name:	Dialysate Concentrate for Hemodialysis (liquid)
Classification Name:	Hemodialysis systems and accessories

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C. Predicate Device Name:

The Fresenius Naturalyte® Liquid Acid Concentrate is a modified version of the Fresenius Naturalyte Liquid Acid Concentrate1996):

- #K810925 (4/23/1981) – 9000 series
- #K823115 (12/3/1982) – 4000 series
- #K852310 (7/26/1985) – 6000 series

D. Device Description/Indications for Use:

The intended use for the modified device is equivalent to that of the unmodified device:

Intended Use

Acid Concentrate for Bicarbonate Dialysis

E. Substantial Equivalence:

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Naturalyte Liquid Acid Concentrates are a device pursuant to 21 CFR §201 [321] (h).

2. Does the new device have the same intended use?

YES – The intended use for the modified devices are equivalent to the unmodified devices.

Fresenius modified Fresenius Naturalyte Liquid Acid Concentrates - Intended Use

Acid Concentrate for Bicarbonate Dialysis

Fresenius unmodified Fresenius Naturalyte Liquid Acid Concentrates - Intended Use

Acid Concentrate for Bicarbonate Dialysis

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3. Does the device have technological characteristics that raise new types of safety or effectiveness questions?

NO – The Fresenius Naturalyte Liquid Acid Concentrates are a modified version of the Fresenius Naturalyte Liquid Acid Concentrates. The technological characteristics of the modified devices are equivalent to those of the unmodified devices and raise no new types of safety or effectiveness questions.

4. Does descriptive or performance information demonstrate equivalence?

YES – Fresenius Medical Care North America believes that the information provided in this submission clearly describes the modified Fresenius Naturalyte Liquid Acid Concentrates and demonstrates that it is substantially equivalent to the unmodified devices.

F. Safety Summary

The Fresenius modified Naturalyte Liquid Acid Concentrates are substantially equivalent in construction, design, materials, and intended use to the commercially available Fresenius Naturalyte Liquid Acid Concentrates. In addition, testing of the modified device indicates that the set is safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The Fresenius modified Naturalyte Liquid Acid Concentrates is to be used with a three-stream proportioning systems when calibrated to specified proportions depending on the series and mixed with water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. Not for Parenteral Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 2 9 2007

Ms. Janet C. Kay
Manager of Regulatory Affairs
Fresenius Medical Care North America
920 Winter Street
WALTHAM MA 02451

Re: K070177
Trade/Device Name: Fresenius Naturalyte® Liquid Acid Concentrates, 9000, 6000 and 4000 Series
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: February 26, 2007
Received: February 28, 2007

Dear Ms. Kay:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Enclosure

Fresenius Medical Care

Indications for Use

510(k) Number (if known): K070177

Device Name: Fresenius Naturalyte® Liquid Acid Concentrates, 9000, 6000 and 4000 Series.

Indications for Use:

Acid Concentrate for Bicarbonate Dialysis

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070177

(Posted November 13, 2003)

Fresenius Medical Care North America
Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000