K030497

Fresenius Naturalyte® Granuflo® Dry Acid Concentrate
510(k) Premarket Notification

MAY 2 0 2003

510K Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the Fresenius Naturalyte® Granuflo® Dry Acid Concentrate.

Company: Art Eilinsfeld, Director of Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Ave.
Lexington, MA 02420
1-800-662-1237

Date: January 14, 2003

Trade Name: Fresenius Naturalyte® Granuflo® Dry Acid Concentrate

Common Name: Dialysate concentrate for hemodialysis (liquid or powder)

Classification Name and Reference: 21 CFR §876.5820 Dialysate concentrate for hemodialysis (liquid or powder) – Class II

Device Product Code and Panel Code: KPO, 78

Predicate Device(s): Granulyte Powder Dialysate Concentrates and Mixer; (K911459, SE 07/17/1991); Granulyte Dialysate Concentrate; (K922005, SE 03/30/94)

Description:
The Fresenius Naturalyte® Granuflo® Dry Acid Concentrate is designed to be used as direct product replacement for the current Granuflo® Concentrate (Series 1000, 2400, and 3000). The new product will be available in a non-granulated formula. It is used only during hemodialysis. It is manufactured using the same raw materials. The new Fresenius Naturalyte® Granuflo® Dry Acid Concentrate has the same chemical composition as the predicate devices. It is for single use only. It is supplied non-sterile and is non-pyrogenic.

Intended Use:
The Fresenius Naturalyte® Granuflo® Dry Acid Concentrate is indicated in the treatment of acute and chronic renal failure during the hemodialysis procedure. This concentrate is formulated to be used with a three-stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates.

Safety and Performance:
The intended use, technological characteristics, design features, and materials are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of the Fresenius Naturalyte® Granuflo® Dry Acid Concentrate is supported by the substantial equivalence information, materials data, device description, and performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Mr. Arthur Eilinsfeld
Director of Regulatory Affairs
Fresenius Medical Care North America
95 Hayden Avenue
LEXINGTON MA 02173

Re: K030497
Trade/Device Name: Fresenius Naturalyte® Granuflo® Dry Acid Concentrate
Regulatory Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: February 14, 2003
Received: February 19, 2003

Dear Mr. Eilinsfeld:

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 (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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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,

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 Statement

Device Name:

Fresenius Naturalyte® Granuflo® Dry Acid Concentrate

Indications for Use:

The Fresenius Naturalyte® Granuflo® Dry Acid Concentrate is indicated in the treatment of acute and chronic renal failure during the hemodialysis procedure. This concentrate is formulated to be used with a three-stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030497