



USER: POIRIER, LORI L (llw)

FOLDER: K070177 - 191 pages (FOI:07004048)

COMPANY: FRESENIUS MEDICAL CARE NORTH AMERICA (FRESMEDICARENORA)

PRODUCT: DIALYSATE CONCENTRATE FOR HEMODIALYSIS (LIQUID OR POWDER) (KPO)

SUMMARY: Product: FRESENIUS NATURALYTE LIQUID ACID CONCENTRATE, 9000, 6000 AND 4000 SERI

DATE REQUESTED: Tue Sep 16 24:00:00 2008

DATE PRINTED: Tue Feb 24 09:23:21 2009

Note: Releasable Version

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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



Fresenius Medical Care

Fresenius Naturalyte® Liquid Acid Concentrates “Special” 510(k) Premarket Notification Summary of Safety and Effectiveness

C. Predicate Device Name:

The Fresenius Naturalyte® Liquid Acid Concentrate is a modified version of the Fresenius Naturalyte Liquid Acid Concentrate (1996):

- #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



Fresenius Medical Care

Fresenius Naturalyte® Liquid Acid Concentrates “Special” 510(k) Premarket Notification Summary of Safety and Effectiveness

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 29 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.



Protecting and Promoting Public Health

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.

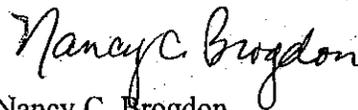
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
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)

David M. Ageman
 Concurrency of CDRH, Office of Device Evaluation (ODE)
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K070177

Page __ of __

(Posted November 13, 2003)

Fresenius Medical Care North America

Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 29 2007

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920 Winter Street
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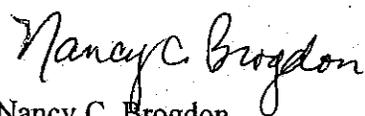
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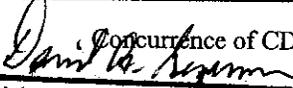
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Prescription Use
(Part 21 CFR 801 Subpart D)

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

Page of

(Posted November 13, 2003)

Fresenius Medical Care North America

Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

(b) (4)

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the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at:
<http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, “Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment”. If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

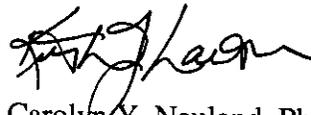
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Page 3 – Ms. Janet Kay

If you have any questions concerning the contents of the letter, please contact Jeffrey Cooper, D.V.M. at (240) 276-4151. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 3 – Ms. Janet Kay

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Sincerely yours,

for Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-470 DRARD
D.O.

HFZ470:JeffCooper:GHG:lrn:2.8.2007

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 470	Cooper	2/7/07						
HFZ-470	JK	2/9/07						

U.S. GPO 1986-169-089

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 19, 2007

FRESENIUS MEDICAL CARE NORTH AMERIC 510(k) Number: K070177
920 WINTER ST. Received: 18-JAN-2007
WALTHAM, MA 02451 Product: FRESENIUS NATURALYTE
ATTN: JANET C. KAY LIQUID ACID
CONCENTRATE, 9000,
6000 AND 4000 SERIES

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K070177

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) (b)(4) Write the Payment Identification number on your check.
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A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) FRESENIUS MEDICAL CARE NORTH AMERICA 920 Winter Street Waltham MA 02451 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4) (b)(4)	2. CONTACT NAME Janet Kay 2.1 E-MAIL ADDRESS janet.kay@fmc-na.com 2.2 TELEPHONE NUMBER (include Area code) 781-699 4475 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 781-699 -9635
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GU II

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/dc/mdufma>)

<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	<u>3.1 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
---	---

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) (b)(4)

16-Jan-2007

Form FDA 3601 (08/2003)

"Close Window" Print Cover sheet

K32

39



Fresenius Medical Care

January 16, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: Special 510(k) Premarket Notification for a change to the manufacturing process of Naturalyte® Liquid Acid Concentrate

Dear Sir or Madam:

Fresenius Medical Care North America intends to begin marketing the Naturalyte Liquid Acid Concentrate using a modified manufacturing process. Two copies of this Special 510(k) Premarket Notification are enclosed.

All items Fresenius Medical Care North America considers proprietary, i.e., not to be disclosed under the Freedom of Information Act, are marked "CONFIDENTIAL."

If you have any questions, please feel free to contact me at 781-699-4475.

Sincerely,

Janet C. Kay
Manager of Regulatory Affairs

Attachment

Fresenius Medical Care North America

Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 1/16/07	User Fee Payment ID Number MD 6029407-956733	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission Amendment Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission Amendment Supplement Report Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Fresenius Medical Care North America		Establishment Registration Number (if known) 1225714	
Division Name (if applicable)		Phone Number (including area code) (781) 699-4475	
Street Address 920 Winter Street		FAX Number (including area code) (781) 699-9635	
City Waltham	State / Province MA	ZIP/Postal Code 02451	Country USA
Contact Name Janet C, Kay			
Contact Title Manager Regulatory Affairs		Contact E-mail Address janet.kay@fmc-na.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
 - Software / Hardware
 - Color Additive
 - Material
 - Specifications
 - Other (*specify below*)

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

- Process change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (*specify below*)

- Labeling change:
 - Indications
 - Instructions
 - Performance
 - Shelf Life
 - Trade Name
 - Other (*specify below*)

- Report Submission:
 - Annual or Periodic
 - Post-approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

Other Reason (*specify*):

SECTION D2

REASON FOR APPLICATION - IDE

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent / Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

- Repose to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Report submission:
 - Current Investigator
 - Annual Progress Report
 - Site Waiver Report
 - Final

Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

- New Device

- Additional or Expanded Indications

- Change in Technology

Other Reason (*specify*):
Modification to the manufacturing process

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KPO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K810925	Fresenius Naturalyte Liquid Acid Concentrate (9000 Series)	Fresenius Medical Care North America
2	K823115	Fresenius Naturalyte Liquid Acid Concentrate (4000 Series)	Fresenius Medical Care North America
3	K852310	Fresenius Naturalyte Liquid Acid Concentrate (6000)	Fresenius Medical Care North America
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Dialysis concentrate for hemodialysis (liquid)

	Trade or Proprietary or Model Name for This Device	Model Number
1	Fresenius Naturalyte Liquid Acid Concentrate	1 9000 Series
2	Fresenius Naturalyte Liquid Acid Concentrate	2 6000 Series
3	Fresenius Naturalyte Liquid Acid Concentrate	3 4000 Series
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code KPO	C.F.R. Section (if applicable) 876.5820	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel LKN Gastroenterology/Urology		

Indications (from labeling)

Liquid Acid Concentrate for Bicarbonate Dialysis

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 1651896		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Fresenius Medical Care North America			Establishment Registration Number 1651896		
Division Name (if applicable)			Phone Number (including area code) (972) 929-7291		
Street Address 5201 Regent Blvd			FAX Number (including area code) (972) 915-6032		
City Irving, TX		State / Province	ZIP/Postal Code 75063	Country USA	
Contact Name Timothy Poquette		Contact Title Quality Manager		Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 3005162618		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Fresenius Medical Care North America			Establishment Registration Number 3005162618		
Division Name (if applicable)			Phone Number (including area code) (419) 698-7031		
Street Address 750 North Lallendorf Rd.			FAX Number (including area code) (419) 698-7302		
City Oregon		State / Province OH	ZIP/Postal Code 43616	Country	
Contact Name John Leppelmeier		Contact Title Plant Manager		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	13485:1996	ISO	Quality Systems - Medical Devices	2nd edition	07/15/2003
3	14971:2001	ISO/EN	Medical Devices - Application of Risk Management	1st edition	12/15/2000
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

**Fresenius Naturalyte® Liquid Acid Concentrates
 “Special” 510(k) Premarket Notification
 Screening Checklist
 Premarket Notifications [(510(k)] Submissions**

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate	Location
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510]] Manual.			Present
Table of Contents.			Present
Truthful and Accurate Statement.			Present
Device's Trade Name, Device's Classification Name and Establishment Registration Number.			Section I
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).			Section I
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510]] Manual.			Appendix 9
Statement of Indications for Use that is on a separate page in the premarket submission.			Appendix 2
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510]] Manual.			Section II
510(k) Summary or 510(k) Statement.			Appendix 1
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.			Section III, IV

**Fresenius Naturalyte® Liquid Acid Concentrates
 “Special” 510(k) Premarket Notification**

**Screening Checklist
 Premarket Notifications [(510(k)] Submissions**

Identification of legally marketed predicate device. *			Section I
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]			Section I
Class III Certification and Summary. **			N/A
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]			N/A
510(k) Kit Certification ***			N/A

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing	Location
Name and 510(k) number of the submitter’s own, unmodified predicate device.			Section I
A description of the modified device and a comparison to the sponsor’s predicate device.			Section III
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter’s unmodified predicate device.			Appendix 3
Reviewer’s confirmation that the modification has not altered the fundamental scientific technology of the submitter’s predicate device.			
A Design Control Activities Summary that includes the following elements (a-c):			
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.			Section VI, Appendix 6
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.			Section VI

**Fresenius Naturalyte® Liquid Acid Concentrates
 “Special” 510(k) Premarket Notification
 Screening Checklist
 Premarket Notifications [(510(k)] Submissions**

c. A Declaration of Conformity with design controls that includes the following statements:			Appendix 8
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.			Appendix 8
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.			Appendix 8

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that		

**Fresenius Naturalyte® Liquid Acid Concentrates
 “Special” 510(k) Premarket Notification
 Screening Checklist
 Premarket Notifications [(510(k)] Submissions**

supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		-
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the “Present or Adequate” column do not require additional information from the sponsor. Items with checks in the “Missing or Inadequate” column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

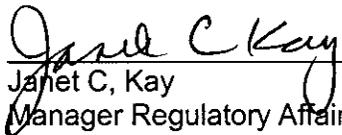
Concurrence by Review Branch: _____

Date: _____

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

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT.

I certify that, in my capacity as Manager of Regulatory Affairs for Fresenius Medical Care North America, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Janet C. Kay
Manager Regulatory Affairs



Date

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification**

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**Fresenius Naturallyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification**

Section I: General Device Summary

Proprietary Name: Fresenius Naturallyte Liquid Acid Concentrates
(4000, 6000, and 9000 Series)

Common Name: Dialysate Concentrate for Hemodialysis (liquid)

Product Code/Classification Panel: 78 KPO Gastroenterology/Urology

Classification: Class II per §876.5820

Establishment Registration

Manufacturing Facility Address:

Fresenius Medical Care North America
5201 Regent Blvd
Irving, TX 75063

FDA Establishment Registration Number: 1651896

Fresenius Medical Care North America
750 North Lallendorf Rd.
Oregon OH 43616

FDA Establishment Registration Number: 3005162618

Submitter Information

Submitter's Name and Address:

Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451-1457

FDA Establishment Registration Number: 1225714

Contact Information:

Janet C. Kay
Manager Regulatory Affairs
Telephone: (781) 699-4475
Fax: (781) 699-9635

Alternate Contact
Art Eilinsfeld
Director Regulatory Affairs
Telephone: (781) 699-9068

Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section I: General Device Summary

Summary of Safety and Effectiveness

The 510(k) Summary of Safety and Effectiveness is provided in **Appendix 1- Summary of Safety and Effectiveness**.

Performance Standards

No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act for dialysate concentrates for hemodialysis (liquid or powder).

Propose of the Special 510(k) Submission

The purpose of this submission is to describe a manufacturing process change for Naturalyte Liquid Acid Concentrates. The change is the use of Granuflo® bags which are a nonconforming material for Granuflo and use it as a raw material for the manufacturing of Naturalyte Liquid Acid Concentrates. This is a cost saving measure to the manufacturing process and well as optimizing efficiency in the manufacturing plants. Like Naturalyte, Granuflo (K030497) is a dry acid concentrate used for bicarbonate dialysis

Predicate Device

The Fresenius Naturalyte Liquid Acid Concentrates are a modified version of the FDA cleared Naturalyte Liquid Acid Concentrates:

Fresenius unmodified Naturalyte Liquid Acid Concentrates

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

Indications for Use/Intended Use

Acid Concentrate for Bicarbonate Dialysis

The Indications for Use statement is provided in **Appendix 2- Indications for Use Statement**.

A statement that the intended use and indications of the modified device, as described in the labeling is the same as the intended use and indication for the submitter’s unmodified predicate device is provided in **Appendix 3**.

Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section II: Statement of Substantial Equivalence

Statement of Substantial Equivalence

Fresenius Medical Care North America believes that, within the meaning of the Medical Device Amendments of 1976, the Fresenius Naturalyte Liquid Acid Concentrates addressed in this Special 510(k) premarket notification are substantially equivalent to the following medical devices in commercial distribution:

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

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

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

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification**

Section II: Statement of Substantial Equivalence

Concentrates and demonstrates that it is substantially equivalent to the unmodified devices.

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section III: Description of Liquid Acid Reformulation**

(b) (4)

(b)(4)

56

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section III: Description of Liquid Acid Reformulation**

(b) (4)

(b)(4)

57

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section III: Description of Liquid Acid Reformulation**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section III: Description of Liquid Acid Reformulation**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section III: Description of Liquid Acid Reformulation**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b)(4)

(b)(4)

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**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

63

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**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

65

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b)(4)

(b)(4)

66

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b)(4)

(b)(4)

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**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
"Special" 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b) (4)

(b)(4)

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**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section IV: Description of Manufacturing Process**

(b)(4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification**

Section V: Comparison of Unmodified Device to Modified Device

(b)(4)

(b)(4)

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**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification**

Section V: Comparison of Unmodified Device to Modified Device

(b) (4)

(b)(4)

**Fresenius Naturalyte® Liquid Acid Concentrates
“Special” 510(k) Premarket Notification
Section VI: Summary of Design Control Activities**

Risk Analysis

The risk analysis is provided in **Appendix 6**. Risks and their respective mitigation have been identified.

Design Validation

All verification activities to demonstrate (b) (4) (b)(4)
(b) (4) (b)(4)
(b) (4) (b)(4) The Dry Acid
Reformulation Master Validation Plan is provided in **Appendix 7**.

Declaration of Conformity with Design Controls

A declaration of conformity with design controls is provided in **Appendix 8 - Declaration of Conformity with Design Controls**.

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

Section VII: Labeling and Packaging

Labeling

Copies of the labeling are provided in **Appendix 9– Labeling**.

Please Note: The corporate address for Fresenius Medical Care North America has changed. The new address is

920 Winter Street
Waltham MA, 02451
1-800-323-5188

The labels are currently being modified to change the address. However, the modification is not reflected in the labels included. No other information is being changed as a result of the address change.

Packaging

The modified devices will be packaged in the same packaging system used for the unmodified devices.



Fresenius Medical Care

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:

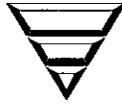
Name: Fresenius Medical Care North America
Address: 920 Winter Street
Waltham, MA 02451

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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Fresenius Medical Care

Fresenius Naturalyte® Liquid Acid Concentrates “Special” 510(k) Premarket Notification Summary of Safety and Effectiveness

C. Predicate Device Name:

The Fresenius Naturalyte® Liquid Acid Concentrate is a modified version of the Fresenius Naturalyte Liquid Acid Concentrate (1996):

- #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



Fresenius Medical Care

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

Summary of Safety and Effectiveness

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.



Fresenius Medical Care

Indications for Use

510(k) Number (if known): _____

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)

Page __ of __

(Posted November 13, 2003)

Fresenius Medical Care North America

Corporate Headquarters: 95 Hayden Avenue Lexington, MA 02420 (781) 402-9000

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Fresenius Medical Care

Statement that the intended use/indication for use of the modified device is the same as the unmodified device

The Fresenius Naturalyte Liquid Acid Concentrate has the same intended use/indications for use as the unmodified Naturalyte Liquid Acid Concentrate. The intended use/indications for use statement as it appears in the labeling for this device, appears on the product labels. It has not been altered or changed in any way as a result of the modification to the Naturalyte Liquid Acid Concentrates.

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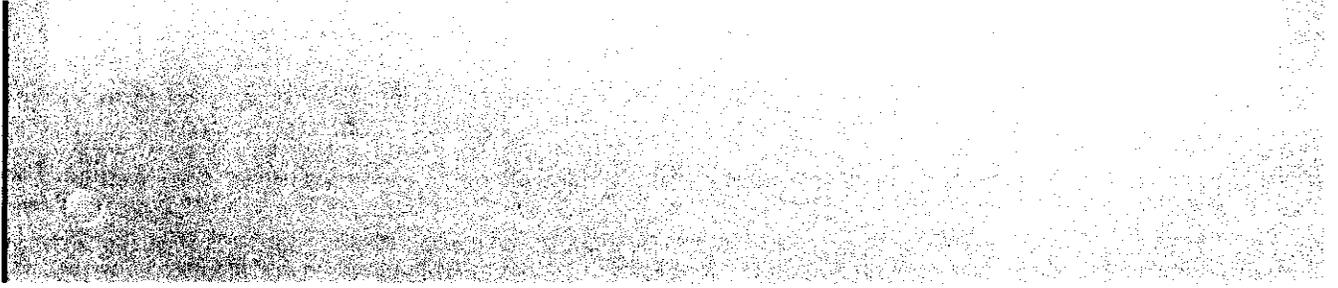
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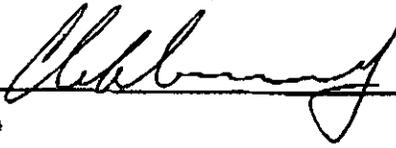
147



Fresenius Medical Care

Verification Activities

To the best of my knowledge, as required by the risk analysis, all verification activities have been completed by the designated individuals(s) and the results demonstrated that the predetermined acceptance criteria were met.



 Name 1/16/07

 Date

 IMPA2 LEADER

 Title

Manufacturing Facility

The manufacturing facility:

is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



 Name 1/16/07

 Date

 QUALITY SYSTEMS MANAGER

 Title

1/14/07

148

WARNING: For use only with in-line proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4002

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	2.0	
CALCIUM	3.0	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	105.75	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	6.71 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	7.49 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 105.75 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



CAT. NO. **13-4002-5**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2813.08: 05/03

179

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4003

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100 mEq/L
POTASSIUM	1.0
CALCIUM	3.0
MAGNESIUM	0.75
ACETATE	4.0
CHLORIDE	104.75
DEXTROSE	200 mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	3.35 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	7.49 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 104.75 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

LOT NO.

CAT. NO. **13-4003-3**

Printed in U.S.A. 71-2814-08-05/09

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4005

4000 Series
Acid Concentrate for Bicarbonate Dialysis 208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	3.0	
CALCIUM	3.0	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	106.75	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	10.06 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	7.49 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 106.75 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain the same.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
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95 Hayden Avenue
Lexington, MA 02420
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EXPIRATION
DATE

LOT NO.

CAT. NO. **13-4005-8**

Printed in U.S.A. 71-3226.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4010

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	2.0	
CALCIUM	2.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	105.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	6.71 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	6.24 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 105.25 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain the same.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
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95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-4010-8**

EXPIRATION
DATE

LOT NO.

Printed in U.S.A. 71-2763.07 0503

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte™ 4013

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	2.0	
CALCIUM	3.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	106.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	3.43 g
KCl	6.71 g	CH ₃ CO ₂ H	10.81 g
CaCl ₂	11.58 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte™ 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 106.25 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. **Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.** Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

LOT NO.

CAT. NO. **13-4013-7**

Printed in U.S.A. 71-4218-00 01/06

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WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4018

4000 Series
Acid Concentrate for Bicarbonate Dialysis (208.2 Liters (55 Gallons))

Intrinsic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	1.0	
CALCIUM	2.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	104.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	3.36 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	6.24 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 104.25 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain the same.

CAUTION:

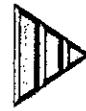
Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-4018-1**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2784-07 05/03

154

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4022

4000 SERIES
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SSODIUM	100	mEq/L
POTASSIUM	0	
CALCIUM	2.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	103.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	0 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	6.24 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 103.25 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain the same.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-4022-3**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2817-07 05/03

55

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 4027

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	3.0	
CALCIUM	2.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	106.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	1.61 g
KCl	10.07 g	CH ₃ CO ₂ H	10.80 g
CaCl ₂	6.24 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte® 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 106.25 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain the same.

CAUTION:

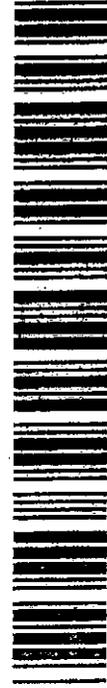
Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-4027-2**

Printed in U.S.A. 71-2765.07 05/03

EXPIRATION DATE

LOT NO.

156

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte™ 4032

4032 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	2.0	
CALCIUM	2.0	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	104.75	
DEXTROSE	200	mg/dL

Chemical Composition of Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	3.43 g
KCl	6.71 g	CH ₃ CO ₂ H	10.81 g
CaCl ₂	6.62 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte™ 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 104.75 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Taubman Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-4032-2**

EXPIRATION DATE

LOT NO.

Printed In U.S.A. 71-4216-00 01/06

157

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte™ 4067

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	2.0	
CALCIUM	2.25	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	105.00	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	3.43 g
KCl	6.71 g	CH ₃ CO ₂ H	10.81 g
CaCl ₂	7.44 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte™ 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 105.00 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

CAT. NO. **13-4067-3**

Printed in U.S.A. 71-4217.00 01/06

LOT NO.

158

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte™ 4068

4000 Series
Acid Concentrate for Bicarbonate Dialysis **208.2 Liters (55 Gallons)**

Ionic Contribution of Acid Concentrate
 (Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	1.0	
CALCIUM	2.25	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	104.00	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	3.43 g
KCl	3.35 g	CH ₃ CO ₂ H	10.81 g
CaCl ₂	7.44 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte™ 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 104.00 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:
Fresenius Medical Care
 95 Hayden Avenue
 Lexington, MA 02420
 1-800-323-5188



CAT. NO. **13-4068-5**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-4215-00 0106

159

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte™ 4069

4000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:44)

SODIUM	100	mEq/L
POTASSIUM	3.0	
CALCIUM	2.25	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	106.00	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	263.0 g	MgCl ₂	3.43 g
KCl	10.06 g	CH ₃ CO ₂ H	10.81 g
CaCl ₂	7.44 g	C ₆ H ₁₂ O ₆	90.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.72 parts base concentrate (Naturalyte™ 4000 Series bicarbonate) and 42.28 parts water, the final ionic composition is: sodium 137 mEq/L; chloride 106.00 mEq/L; and net bicarbonate 33 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION DATE

CAT. NO. **13-4069-2**

LOT NO.

Printed in U.S.A. 71-4219.00 01/06

160

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. NOT FOR PARENTERAL USE.

Naturalyte® 6601

6000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	103	meq/L
POTASSIUM	2.0	
CALCIUM	3.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	109.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (µm/L)

NaCl	210.7 g	MgCl ₂	1.67 g
KCl	5.22 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	5.80 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 138 mEq/L; chloride 109.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

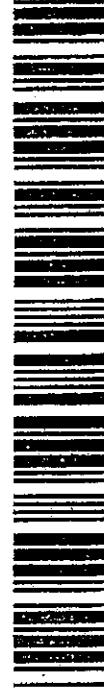
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Heyden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-6601-2**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-1742.07 05/03

161

110

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. NOT FOR PARENTERAL USE.

Naturalyte® 6602

6000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	103	mEq/L
POTASSIUM	3.0	
CALCIUM	3.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	110.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (µm/L)

NaCl	210.7 g	MgCl ₂	1.67 g
KCl	7.83 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	6.80 g	C ₁₂ H ₂₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 138 mEq/L; chloride 110.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

LOT NO.

CAT. NO. **13-6602-0**

Printed in U.S.A. 71-1743.07 05/03

162

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6607

6000 Series
Acid Concentrate for Bicarbonate Dialysis (208.2 Liters (55 Gallons))

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	105	mEq/L
POTASSIUM	2.0	
CALCIUM	3.0	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	111	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	214.8 g	MgCl ₂	1.67 g
KCl	5.22 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	5.83 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 111 mEq/L; and net bicarbonate 92 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-6607-9**

EXPIRATION
DATE

LOT NO.

Printed in U.S.A. 71-1746.07 05/03

163

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6608

6000 Series
Acid Concentrate for Bicarbonate Dialysis
 208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
 (Nominal Dilution 1:34)

SODIUM	103	mEq/L
POTASSIUM	1.0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	107.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	210.7 g	MgCl ₂	1.67 g
KCl	2.51 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	4.86 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 138 mEq/L; chloride 107.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
 95 Hayden Avenue
 Lexington, MA 02420
 1-800-333-5188



EXPIRATION
 DATE

LOT NO.

CAT. NO. **13-6608-7**

Printed in U.S.A. 71-2246-07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6611

6000 Series
Acid Concentrate for Bicarbonate Dialysis 208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	105	mEq/L
POTASSIUM	2.0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	110.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	214.8 g	MgCl ₂	1.67 g
KCl	5.22 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	4.86 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1,225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32,775 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 110.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. **Keep container tightly closed when not in use.**

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
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95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

LOT NO.

CAT. NO. **13-6611-1**

Printed in U.S.A. 71-2095.07 05/03

165

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6614

6000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	105	mEq/L
POTASSIUM	0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	108.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	214.8 g	MgCl ₂	1.67 g
KCl	0 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	4.86 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1,225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32,775 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 108.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION
DATE

CAT. NO. **13-6614-5**

LOT NO.

Printed in U.S.A. 71-2823.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6615

6000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	105	mEq/L
POTASSIUM	3.0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	111.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	214.8 g	MgCl ₂	1.67 g
KCl	7.93 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	4.86 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 111.5 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5198



EXPIRATION DATE

CAT. NO. **13-6615-2**

LOT NO.

Printed in U.S.A. 71-2959.07 06/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 34 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 6619

6000 Series
Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:34)

SODIUM	105	mEq/L
POTASSIUM	1.5	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	3.0	
CHLORIDE	110	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	214.8 g	MgCl ₂	1.67 g
KCl	3.91 g	CH ₃ CO ₂ H	6.31 g
CaCl ₂	4.86 g	C ₆ H ₁₂ O ₆	70.00 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.225 parts base concentrate (Naturalyte® 6000 Series bicarbonate) and 32.775 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 110 mEq/L; and net bicarbonate 32 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. **Mix thoroughly before use.**

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



LOT NO. **13-6619-4**

EXPIRATION DATE

Printed in U.S.A. 71-4143.00 09/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 8801

35.83% Sodium Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	79	mEq/L
POTASSIUM	2.0	
CALCIUM	3.5	
MAGNESIUM	1.5	
ACETATE	4.0	
CHLORIDE	86	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

HCl	170.0 g	MgCl ₂	2.63 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	7.15 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 138 mEq/L; chloride 106 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-8801-6**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-3228-07-05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. NOT FOR PARENTERAL USE.

Naturalyte® 9008

208.2 Liters (55 Gallons)

Acid Concentrate for Bicarbonate Dialysis

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	80	mEq/L
POTASSIUM	3.0	
CALCIUM	3.0	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	87	
DEXTROSE	250	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	172.2 g	MgCl ₂	1.75 g
KCl	8.24 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	6.13 g	C ₆ H ₁₂ O ₆	92.08 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 139 mEq/L; chloride 107 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9008-7**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-5445.05 05/09

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. NOT FOR PARENTERAL USE.

36.83% Naturalyte® 9012

208.2 Liters (55 Gallons)

Acid Concentrate for Bicarbonate Dialysis

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	80	mEq/L
POTASSIUM	1.0	
CALCIUM	3.5	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	85.5	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	172.2 g	MgCl₂	1.75 g
KCl	2.75 g	CH₃CO₂H	8.85 g
CaCl₂	7.15 g	C₆H₁₂O₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 139 mEq/L; chloride 105.5 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

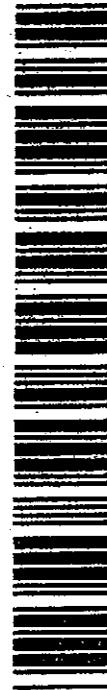
Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION DATE

CAT. NO. **13-9012-9**

Printed in U.S.A. 71-2111.07 05/03

LOT NO.

171

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 9013

208.2 Liters (55 Gallons)

Acid Concentrate for Bicarbonate Dialysis

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	80	mEq/L
POTASSIUM	2.0	
CALCIUM	3.5	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	86.5	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	172.2 g	MgCl ₂	1.75 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	7.15 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 139 mEq/L; chloride 106.5 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

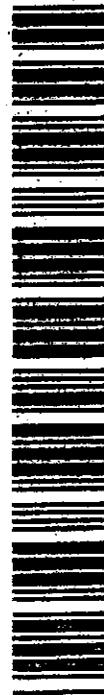
Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
93 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION DATE

LOT NO.

CAT. NO. **13-9013-7**

Printed in U.S.A. 71-2112.07 08/09

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

30-80X Naturalyte® 9018

Anticoagulant for Bicarbonate Dialysis (208.2 Liters (55 Gallons))

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	79	mEq/L
POTASSIUM	2.0	
CALCIUM	2.5	
MAGNESIUM	1.5	
ACETATE	4.0	
CHLORIDE	85	
DEXTROSE	100	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	170.0 g	MgCl ₂	2.63 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	5.11 g	C ₆ H ₁₂ O ₆	36.83 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 138 mEq/L; chloride 105 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

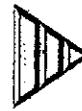
Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:

Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9018-6**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2116.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

35.83% Naturalyte® 9019

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	1.0	
CALCIUM	2.5	
MAGNESIUM	0.7	
ACETATE	4.0	
CHLORIDE	85.2	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3 g	MgCl ₂	1.23 g
KCl	2.75 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	5.11 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 105.2 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9019-4**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2117.07 05/03

174

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 9025

35.83% Sodium Bicarbonate Dialysis **208.2 Liters (55 Gallons)**

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	80	mEq/L
POTASSIUM	0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	83.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	172.2	g	MgCl₂	1.75	g
KCl	0	g	CH₃CO₂H	8.85	g
CaCl₂	5.11	g	C₆H₁₂O₆	73.66	g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 139 mEq/L; chloride 103.5 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.
Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-373-5188



EXPIRATION
DATE

LOT NO.

CAT. NO. **13-9025-1**

Printed in U.S.A. 71-2122.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 9027

35.83% Bicarbonate Concentrate **208.2 Liters (55 Gallons)**

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	2.0	
CALCIUM	2.5	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	86.5	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3	g	MgCl₂	1.75	g
KCl	5.49	g	CH₃CO₂H	8.85	g
CaCl₂	5.11	g	C₆H₁₂O₆	73.56	g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 106.5 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

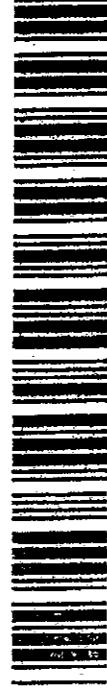
Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9027-7**

EXPIRATION
DATE

LOT NO.

Printed in U.S.A. 71-2286.07 05/09

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

NaturaLyte® 9035

208.2 Liters (55 Gallons)

HEMODYNAMIC ACIDIC DIALYSIS

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	2.0	
CALCIUM	3.0	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	87	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3 g	MgCl ₂	1.75 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	6.13 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (NaturaLyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 107 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9035-0**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-2551.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

9000x Naturalyte[®] 9041

Acid Concentrate for Bicarbonate Dialysis

208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	2.0	
CALCIUM	2.0	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	86	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (µm/L)

NaCl	174.3 g	MgCl ₂	1.75 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	4.09 g	C ₁₂ H ₂₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dilysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte[®] 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 106 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use.

Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:



Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9041-8**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-3060.07 05/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 9062

35.83% Bicarbonate Dialysis **208.2 Liters (55 Gallons)**

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	3.0	
CALCIUM	2.5	
MAGNESIUM	0.75	
ACETATE	4.0	
CHLORIDE	87.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174 g	MgCl ₂	1.3 g
KCl	8.2 g	CH ₃ CO ₂ H	8.8 g
CaCl ₂	5.1 g	C ₆ H ₁₂ O ₆	74.00 g

NON-PYROGENIC

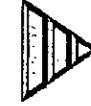
Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 107.25 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

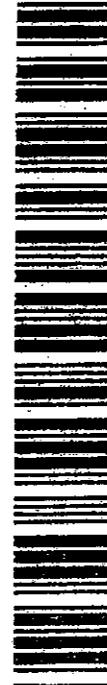
Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:
Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION DATE

CAT. NO. **13-9062-4**

Printed in U.S.A. 71-3446 .05 05/03

LOT NO.

179

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

9067

Naturalyte® 9067

90.85% Bicarbonate Dialysis 208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	2.0	
CALCIUM	2.25	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	86.25	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3 g	MgCl ₂	1.75 g
KCl	5.49 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	4.60 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 106.25 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:

Fresenius Medical Care
 95 Hayden Avenue
 Lexington, MA 02420
 1-800-323-5188



LOT NO. _____ CAT. NO. **13-9067-3** EXPIRATION DATE _____
 Printed in U.S.A. 71-4142.00 08/03

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

Naturalyte® 9068

208.2 Liters (55 Gallons)

Naturalyte® Bicarbonate Dialysis

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	1.0	
CALCIUM	2.25	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	85.25	
DEXTRROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3 g	MgCl ₂	1.75 g
KCl	2.75 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	4.60 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 105.25 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufactured By:

Fresenius Medical Care
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



EXPIRATION DATE

LOT NO.

CAT. NO. **13-9068-5**

Printed in U.S.A. 71-4185-00 09/04

WARNING: For use only with three-stream proportioning systems when calibrated to proportion 1 part acid to 35.83 parts bicarbonate base and water. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. **NOT FOR PARENTERAL USE.**

36.83% Naturalyte® 9069

36.83% Bicarbonate Dialysis 208.2 Liters (55 Gallons)

Ionic Contribution of Acid Concentrate
(Nominal Dilution 1:35.83)

SODIUM	81	mEq/L
POTASSIUM	3.0	
CALCIUM	2.25	
MAGNESIUM	1.0	
ACETATE	4.0	
CHLORIDE	87.25	
DEXTROSE	200	mg/dL

Chemical Composition Acid Concentrate (gm/L)

NaCl	174.3 g	MgCl ₂	1.75 g
KCl	8.24 g	CH ₃ CO ₂ H	8.85 g
CaCl ₂	4.60 g	C ₆ H ₁₂ O ₆	73.66 g

NON-PYROGENIC

Nominal Dialysate Composition: When 1 part acid concentrate is mixed with 1.83 parts base concentrate (Naturalyte® 9000 Series bicarbonate) and 34 parts water, the final ionic composition is: sodium 140 mEq/L; chloride 107.25 mEq/L; and net bicarbonate 35 mEq/L. All other constituents remain unchanged.

CAUTION:

Proper Dilution: Use purified water that meets or exceeds current ANSI/AAMI hemodialysis water quality standards. Refer to the directions for use provided in the dialysis machine operator's manual. Check conductivity (information is available from manufacturer) and pH of dialyzing fluid before starting treatment and each time solution is added.

Use only as directed. Recommended Storage: Avoid excessive heat and protect from freezing. Do not use if seals or container are damaged. Mix thoroughly before use. Keep container tightly closed when not in use.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Manufactured By:
 **Fresenius Medical Care**
95 Hayden Avenue
Lexington, MA 02420
1-800-323-5188



CAT. NO. **13-9069-2**

EXPIRATION DATE

LOT NO.

Printed in U.S.A. 71-4186.00 09/04

182

Division of Reproductive, Abdominal,
and Radiological Devices
HFZ-470

DHHS/PHS/FDA/CDRH/ODE

9200 Corporate Blvd.
Rockville, MD 20850

Phone No.: (240) 276-4151
FAX No.: (240) 276-4156

TO: Ms. Janet Kay
Manager, Regulatory Affairs

From: Jeffrey Cooper, D.V.M.
CDRH/ODE/DRARD/GRDB

Comments: Letter for K070177.

Number of Pages: 4
(Including cover sheet)

Please advise if transmission is illegible.

"This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone and return it to us at the above address by mail. Thank you."

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Jeffrey Cooper

Subject: 510(k) Number K070177/SI

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

Truthful and Accurate Statement Requested Enclosed

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

KPO Class II CFR 876.5820

Review: Carolyn Y Newland GRDB 3/28/07
(Branch Chief) (Branch Code) (Date)

Final Review: David A. Seymour 3/29
(Division Director) (Date)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		<input checked="" type="checkbox"/>
2. Did we grant expedited review?		<input checked="" type="checkbox"/>
3. Have you verified that the Document is labeled Class III for GMP purposes?		<input checked="" type="checkbox"/>
4. If, not, has POS been notified?	—	—
5. Is the product a device?	—	—
6. Is the device exempt from 510(k) by regulation or policy?	—	—
7. Is the device subject to review by CDRH?		—
8. Are you aware that this device has been the subject of a previous NSE decision?		—
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		—
10. Are you aware of the submitter being the subject of an integrity investigation?		<input checked="" type="checkbox"/>
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

K070177

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Reviewer: Jeffrey Cooper, D.V.M. **Division/Branch:** DRARD/GRDB, HFZ-470

Device Trade Name: Fresenius Naturalyte Liquid Acid Concentrate

510(k) Number: K070177

Common Name: Liquid acid concentrate dialysate

Regulation/Classification: The device is in 21 CFR § 876.5820, Hemodialysis system and accessories, Product Code 78KPO - dialysate concentrate for hemodialysis (liquid or powder).

Product to Which Compared: Fresenius Naturalyte Liquid Acid Concentrate (6000) (K852310); (4000 Series) (K823115, and 9000 Series) (K810925).

Company: Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Contact: Janet Kay **Phone:** 781 699-4475
Manager Regulatory Affairs **FAX:** 781 699-9635

	YES	NO*	
1. IS PRODUCT A DEVICE?	√	—	IF NO STOP
2. DEVICE SUBJECT TO 510(K)?	√		IF NO STOP
3. SAME INDICATION STATEMENT?	√		IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			IF YES STOP → NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	√		IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	√		IF YES STOP → SE IF NO GO TO 10
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			IF YES STOP → NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			IF NO STOP → NE
10. PERFORMANCE DATA AVAILABLE?			IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	—	—	IF YES STOP → SE

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

7

Explanations to the Preceding Checklist:

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: See Below.
2. DEVICE DESCRIPTION: See Below.

C Neuland
3/28/07

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE RE: **K070177– Fresenius – Naturalyte Liquid Acid Concentrate**

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From: Reviewer(s) - Name(s) Jeffrey Cooper
Subject: 510(k) Number K070177

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Is this a prescription device?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Special 510(k)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	<input type="checkbox"/> YES	<input type="checkbox"/> NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: <u>[Signature]</u>	<u>BR06</u>	<u>2/9/07</u>
(Branch Chief)	(Branch Code)	(Date)

Final Review: _____	_____
(Division Director)	(Date)

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		
5. Is the product a device?	/	
6. Is the device exempt from 510(k) by regulation or policy?	—	—
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		—
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		—
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE RE: **K070177- Fresenius – Naturalyte Liquid Acid Concentrate**

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**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K070177 – Fresenius – Naturalyte Liquid Acid Concentrate

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling [including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	-	
Class III Certification and Summary. **	n/a	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	n/a	
510(k) Kit Certification ***	n/a	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.	✓	
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓ FMEA	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

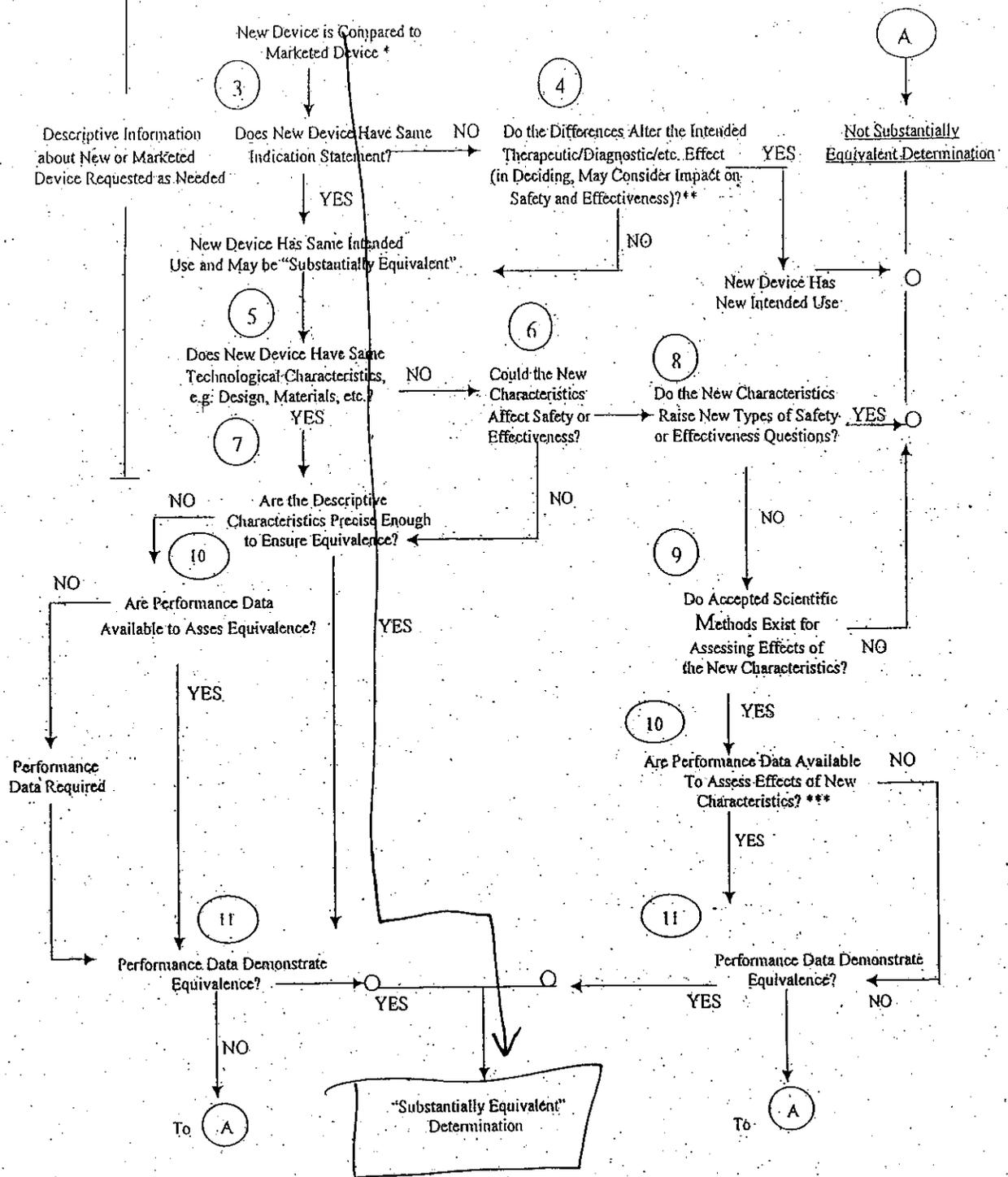
	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

February 28, 2007

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

FRESENIUS MEDICAL CARE NORTH AMERIC 510(k) Number: K070177
920 WINTER ST. Product: FRESENIUS
WALTHAM, MA 02451 NATURALYTE
ATTN: JANET C. KAY LIQUID ACID
CONCENTRATE,

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K070177/S1



Fresenius Medical Care

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

RECEIVED
FEB 28 2007
FDA CDRH DMC

February 26, 2007

Re: K070177
Trade Name: Naturalyte® Liquid Acid Concentrate
Dated: February 12, 2007
Received: February 20, 2007

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Fresenius Medical Care North America

Corporate Headquarters: 920 Winter Street Waltham, MA 02451 (781) 699-9000

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Fresenius Medical Care North America

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Fresenius Medical Care North America

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Appendix 1

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Fresenius Medical Care North America

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Fresenius Medical Care North America

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Fresenius Medical Care North America

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