



USER: CURTSINGER, MARGARET A (mac)

FOLDER: K071387 - 134 pages (FOI:07006371)

COMPANY: FRESENIUS MEDICAL CARE NORTH AMERICA (FRESMEDICARENORA)

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

SUMMARY: Product: FRESENIUS NATURALYTE SODIUM BICARBONATE LIQUID CONCENTRATE, MODEL 08-4

DATE REQUESTED: Thu Oct 09 24:00:00 2008

DATE PRINTED: Thu Jan 29 15:13:57 2009

Note: Releasable Version

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Fresenius Medical Care

JUN 15 2007

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate
"Special" 510(k) Premarket Notification**

510(k) Summary

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: June 14, 2007

B. Device Name:

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



Fresenius Medical Care

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate "Special" 510(k) Premarket Notification

510(k) Summary

C. Predicate Device Name:

The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is a modified version of the Fresenius Biosol Powder Bicarbonate Concentrate

- #K981043 (5/26/1998)

D. Device Description/Indications for Use:

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

Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

E. Substantial Equivalence:

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is 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 device is equivalent to the unmodified device.

Fresenius modified Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates - Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

Fresenius unmodified Biosol Powder Bicarbonate Concentrate - Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

JUN 15 2007



K071387 Page 3 of 3

Fresenius Medical Care

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate "Special" 510(k) Premarket Notification

510(k) Summary

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

NO – The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates is a modified versions of the Biosol Powder Bicarbonate 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® Sodium Bicarbonate Liquid Concentrate and demonstrates that it is substantially equivalent to the unmodified devices.

F. Safety Summary

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrate is substantially equivalent in chemical formulation, chemical composition, and intended use to the commercially available Biosol Powder Bicarbonate Concentrates currently distributed as Fresenius Naturalyte® Dry Pack Bicarbonate Concentrates. In addition, testing of the modified device indicates that the formulations are safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrates are to be used with a three-stream proportioning systems when calibrated to specified proportions depending on the series and mixed with water that meet ANSI/AAMI RD 62.. 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

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

JUN 15 2007

Re: K071387
Trade/Device Name: Fresenius Naturalyte[®] Sodium Bicarbonate Liquid
Concentrates, (4000 Series)
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: May 16, 2007
Received: May 18, 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.

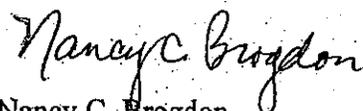
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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): K071387

Device Name:

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates, 4000 Series.

Indications for Use:

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

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 K071387

Page of

(Posted November 13, 2003)

Fresenius Medical Care North America

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

JUN 15 2007

Re: K071387
Trade/Device Name: Fresenius Naturalyte[®] Sodium Bicarbonate Liquid
Concentrates, (4000 Series)
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: May 16, 2007
Received: May 18, 2007

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Protecting and Promoting Public Health

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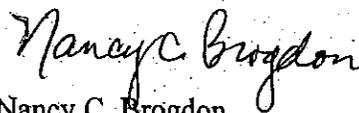
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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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): K071387

Device Name:

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates, 4000 Series.

Indications for Use:

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

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 K071387

Page of

(Posted November 13, 2003)

Fresenius Medical Care North America

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

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

May 18, 2007

FRESENIUS MEDICAL CARE NORTH AMERIC 510(k) Number: K071387
920 WINTER STREET Received: 18-MAY-2007
WALTHAM, MA 02451 Product: FRESENIUS NATURALYTE
ATTN: JANET C. KAY SODIUM BICARBONATE
LIQUID CONCENTRATE,
MODEL 08-40000-LB

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/electsub.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 procedural questions, please contact 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



Fresenius Medical Care

K071387

GU/DRAND

May 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 Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate (4000 series).

Dear Sir or Madam:

Fresenius Medical Care North America intends to begin marketing the Naturalyte Sodium Bicarbonate Liquid Concentrate. Two copies of this Special 510(k) Premarket Notification are enclosed. The second copy is being provided as an electronic copy.

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

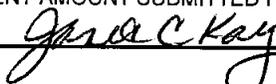
DMC
5/18/07

Attachment

Fresenius Medical Care North America

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

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6030983-956733 Write the Payment Identification number on your check.	
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) 133461988		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	
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)			
Select an application type: <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)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <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) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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"/> 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 sole purpose of the application is to support conditions of use for a pediatric population <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).)			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION \$4,158.00 			
			16-May-2007

Form FDA 3601 (01/2007)

"Close Window" [Print Cover sheet](#)

(b)(4)

(b)(4)



Fresenius Medical Care

May 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 Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate (4000 series).

Dear Sir or Madam:

Fresenius Medical Care North America intends to begin marketing the Naturalyte Sodium Bicarbonate Liquid Concentrate. Two copies of this Special 510(k) Premarket Notification are enclosed. The second copy is being provided as an electronic copy.

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

**Fresenius Naturalyte® Sodium Bicarbonate Liquid
Concentrates
“Special” 510(k) Premarket Notification
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**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“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.			Section VII
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 & V
510(k) Summary or 510(k) Statement.			Appendix 1
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or			Section III

**Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification
Screening Checklist
Premarket Notifications [(510(k)] Submissions**

service manuals.			
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 5

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification
Screening Checklist
Premarket Notifications [(510(k)] Submissions**

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
c. A Declaration of Conformity with design controls that includes the following statements:			Appendix 9
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 9
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 9

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		

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

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

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.

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: _____

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 03/15/2007	User Fee Payment ID Number	FDA Submission Document Number (if known)
----------------------------------	----------------------------	---

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

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: Software /Hardware Color Additive Material Specifications Other (<i>specify below</i>)	<input type="checkbox"/> Location change: Manufacturer Sterilizer Packager
<input type="checkbox"/> Process change: Manufacturing Sterilization Packaging Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: Indications Instructions Performance Shelf Life Trade Name Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment
<input type="checkbox"/> Response to FDA correspondence:	<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address	

Other Reason (*specify*):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: Correspondent / Applicant Design /Device Informed Consent Manufacturer Manufacturing Process Protocol - Feasibility Protocol - Other Sponsor	<input type="checkbox"/> 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
<input type="checkbox"/> Other Reason (<i>specify</i>):		

Other Reason (*specify*):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
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Other Reason (*specify*):
 Modification to a currently cleared device

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	KPO	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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	K981043	Fresenius Biosol Powder Bicarbonate Concentrate (1-XX and 2-XX Series)	Fresenius Medical Care North America
2			
3			
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 Sodium Bicarbonate Liquid Concentrate	08-4000-LB
2		
3		
4		
5		

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

1	K981043	2	K030497	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)
 Bicarbonate 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 Pending		<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 Pending		
Division Name (if applicable) Haemotec Inc.			Phone Number (including area code) (450) 424-3615 x 223		
Street Address 383, Joseph-Carrier			FAX Number (including area code) (450) 424-8199		
City Vandreuil-Dorlon		State / Province Quebec	ZIP/Postal Code J7V SVS	Country Canada	
Contact Name Luce Desroches		Contact Title QA Manager		Contact E-mail Address luce.desroches@fmc-na.com	

<input checked="" 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 OH	ZIP/Postal Code	Country	
Contact Name		Contact Title		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	RD 61:2000	ANSI/AAMI	Concentrates for hemodialysis	2000	06/07/2000
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	RD62:2006	ANSI/AAMI	Water treatment equipment for hemodialysis applications	2006	01/01/2006
5	2007	BP	British Pharmacopeia	2007	01/01/2007
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:

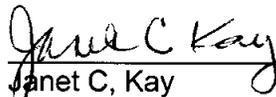
Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

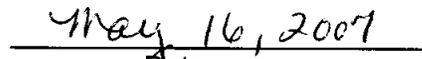
**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
"Special" 510(k) Premarket Notification**

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® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section I: General Device Summary

Proprietary Name: Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates (4000 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:

Haemotec, Inc
383, Joseph-Carrier
Vaudreuil-Dorlon, QC
Canada J7V 5V5

FDA Establishment Registration Number:

Application submitted – pending assignment of registration number

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® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section I: General Device Summary

510(k) Summary

The 510(k) Summary is provided in **Appendix 1- 510(k) Summary**

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 obtain FDA clearance for the Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate (4000 series).

Predicate Device

The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is a modified version of the FDA cleared Biosol Bicarbonate Powder Concentrates (K981043). The Biosol Bicarbonate Powder is currently commercialized as Naturalyte® Dry Pack Bicarbonate 9000, 6000 and 4000 Series sodium bicarbonate powder.

The currently commercialized Naturalyte® Dry Pack Bicarbonate will continue to be commercialized. The modified device is not a replacement for the unmodified device, but a new liquid form of sodium bicarbonate to be used by some customers.

Indications for Use/Intended Use

This concentrate is a liquid sodium bicarbonate concentrate intended 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® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“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® Sodium Bicarbonate Liquid Concentrates addressed in this Special 510(k) premarket notification is substantially equivalent to the following medical device in commercial distribution.

- Biosol Powder Bicarbonate Concentrates #K981043 (May 26, 1998) currently manufactured as Naturalyte® Dry Pack Bicarbonate.
-

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is 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 device is equivalent to the unmodified device.

Fresenius modified Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates - Intended Use

This concentrate is a liquid sodium bicarbonate concentrate intended for bicarbonate dialysis.

Fresenius unmodified Naturalyte® Dry Pack Bicarbonate Concentrates- Intended Use

This concentrate is a dry pack sodium bicarbonate concentrate intended for bicarbonate dialysis.

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

NO – The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is a modified version of the Naturalyte® Dry Pack Bicarbonate Concentrate. The technological characteristics of the modified device are equivalent to that of the unmodified device 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

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section II: Statement of Substantial Equivalence

this submission clearly describes the modified Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates and demonstrates that it is substantially equivalent to the unmodified device.

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification**

Section III: Device Description

Device Description

The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is a liquid concentrate equivalent to Naturalyte® Dry Pack Bicarbonate Concentrate (Biosol Powder Bicarbonate Concentrates) (K981043). The liquid form is not a replacement for the dry pack, but is to be sold in addition to the dry pack. The chemical equivalents and chemical composition will remain identical to that of the unmodified device. Both devices are formulated for use with three stream proportioning bicarbonate systems. The modified product will be

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section IV: Description of Manufacturing Process

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification**

Section IV: Description of Manufacturing Process

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section IV: Description of Manufacturing Process

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section IV: Description of Manufacturing Process

(b) (4)

(b)(4)

**Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section V: Comparison of Modified Device to Unmodified Device

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section V: Comparison of Modified Device to Unmodified Device

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section VI: Summary of Design Control Activities

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section VI: Summary of Design Control Activities

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section VI: Summary of Design Control Activities

(b) (4)

(b)(4)

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section VI: Summary of Design Control Activities

Declaration of Conformity with Design Controls

A declaration of conformity with design controls is provided in **Appendix 9 - Declaration of Conformity with Design Controls**.

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification**

Section VII: Labeling and Packaging

Labeling

At this time the final product label design and layout for the 4000 series has not been decided. However, the text that will be incorporated in the product label has been decided and is being submitted in the following format:

Product Label Text Categories

1. Label color
2. Use of geometric shapes required by AAMI RD61
3. Manufactures name and address
4. Device Name (Trade Name)
5. Catalogue number (Reorder number)
6. Lot Number
7. Directions for Use
8. Expiration date and format
9. Pyrogen claim
10. Chemical composition
11. Fill volume of container
12. Storage requirements
13. Warning
14. Warning
15. Warning
16. Warning
17. Warning
18. Warning
19. Country of Origin
20. Label part number and revision date
21. Customer Service Number

The following tables (VI-1 and VI-2) indicates the text that will be used for each product series in reference to each of the above label categories.

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
"Special" 510(k) Premarket Notification

Section VII: Labeling and Packaging

Naturalyte® 4000 Sodium Bicarbonate Liquid Concentrate

Table VI - 1

Line	Item	Label Text or Graphic as seen on the label
1	Labels color	BLUE triangle
2	Use geometric shapes required by RD61	"BLUE" Triangle 45X
3	Manufacture's name address	FMCNA 920 Winter Street, Waltham MA, 02451 1-800-323-5188
4	Device Name	Naturalyte® Sodium Bicarbonate Liquid Concentrate
5	Catalogue number	08-4000-LB (U.S.) LB-101 (Canada) with Barcode
6	Lot number	Yes, shown as MONTH/2007 12 months from date of manufacturer
7	Directions for Use	Use in accordance with machine operating instructions Check conductivity and pH of dialyzing fluid before starting treatment and each time solution is added (AAMI RD 52) Check for precipitate. Use only if precipitate can be completely dissolved. Once this product is opened, the bicarbonate concentrate must be used within 24 hours. Storage in a closed container is recommended to minimize CO2 loss and resulting precipitation in dialysis equipment. Product must be used before the end of the expiration month (EXP.DATE) on this label.
8	Expiration date and format	Yes, shown as "mm/yyyy". Shelf life is 12 months from date of manufacturer.
9	Pyrogen claim	Solution in un-opened container is non-pyrogenic.
10	Chemical composition	Ionic Contribution of Bicarbonate Concentrate to final dialysate: (Nominal dilution 1:1.72:42.23) Na 37mEq/L HCO ₃ 37mEq/L Chemical Composition:

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification

Section VII: Labeling and Packaging

Line	Item	Label Text or Graphic as seen on the label
		81.25 g/L Sodium Bicarbonate
11	The fill volume of the container	Contents: 6.4 Liters (1.7 U.S. Gallons).
12	Storage requirements	Recommended Storage: Protect from Excessive Heat and Freezing
13	Warning	For use only with three-stream proportioning bicarbonate systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water that meets ANSI/AAMI RD62:2001.
14	Warning	Use with other equipment or without associated acid concentrate may cause patient injury or death.
15	Warning	Not for parenteral use
16	Warning of bacterial growth	Bacterial growth may occur in concentrated bicarbonate solutions. Avoid contamination.
17	Warning	Federal (USA) law restricts this device to sale by or on order of a physician.
18	Warning	Do not use if packaging is damaged or seal is broken.
19	Country of origin	Made in Canada
20	Label part number and rev date	Label part number and revision date
21	Customer Service Number	For US call 1-800-323-5188 For Canada 1-877-633-0013

Copies of the predicate device labeling are provided in **Appendix 9— Labeling**.

**Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series**

“Special” 510(k) Premarket Notification

Section VII: Labeling and Packaging

Packaging

(b) (4)

(b)(4)

Appendix 1



Fresenius Medical Care

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

510(k) Summary

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:

B. Device Name:

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



Fresenius Medical Care

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

510(k) Summary

C. Predicate Device Name:

The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is a modified version of the Fresenius Biosol Powder Bicarbonate Concentrate

- #K981043 (5/26/1998)

D. Device Description/Indications for Use:

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

Intended Use

Bicarbonate Concentrate for Bicarbonate Dialysis

E. Substantial Equivalence:

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate is 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 device is equivalent to the unmodified device.

Fresenius modified Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates - Intended Use

This concentrate is a liquid sodium bicarbonate concentrate intended for bicarbonate dialysis.

Fresenius unmodified Biosol Powder Bicarbonate Concentrate - Intended Use

This concentrate is a powder sodium bicarbonate concentrate intended for bicarbonate dialysis.

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



Fresenius Medical Care

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

510(k) Summary

NO – The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates is a modified versions of the Biosol Powder Bicarbonate 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® Sodium Bicarbonate Liquid Concentrate and demonstrates that it is substantially equivalent to the unmodified devices.

F. Safety Summary

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrate is substantially equivalent in chemical formulation, chemical composition, and intended use to the commercially available Biosol Powder Bicarbonate Concentrates currently distributed as Fresenius Naturalyte® Dry Pack Bicarbonate Concentrates. In addition, testing of the modified device indicates that the formulations are safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrates are to be used with a three-stream proportioning systems when calibrated to specified proportions depending on the series and mixed with water that meet ANSI/AAMI RD 62.. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. Not for Parenteral Use.

Appendix 2



Fresenius Medical Care

Indications for Use

510(k) Number (if known): _____

Device Name:

Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrates, 4000 Series.

Indications for Use:

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

Appendix 3



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® Sodium Bicarbonate Liquid Concentrate has the same intended use/indications for use as the unmodified Biosol Powder Bicarbonate Concentrates currently distributed as Fresenius Naturalyte® Dry Pack Bicarbonate Concentrates. 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® Sodium Bicarbonate Liquid Concentrates.

Fresenius Medical Care North America

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

Appendix 4

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Appendix 5

Failure Mode and Effects Analysis
(Product/Process FMEA)

Item: Liquid Bicarbonate

Process Responsibility: Haemotec, Inc. 383, Joseph-Carrier
Vaudreuil-Dorlon, QC Canada J7V 5V5

Project: Liquid Bicarbonate
Prepared By: Brandi Heckman
FMEA Date (Orig): 3/12/07 (Rev.): 01 (5/15/07)

Product/Process Requirement	Potential Failure Modes	Potential Effect(s) of Failure	S	Potential Cause / Mechanism of Failure	O	Current Process Control Preventions	D	RPN	Status
Raw Material Receipt, Storage, and Use									
Raw materials must meet material specifications	a. OOS raw material	Adverse impact on product performance	4	1. Improper vendor 2. Improper raw material grade 3. Impurity of raw material	1	Vendor qualification requirements Raw material specifications	1	4	Acceptable
All components /materials will be stored and handled to prevent mix-up and properly identified as to test status.	a. Wrong material used for production	OOS product Adverse impact on product and system performance. Adverse patient effects	4	1. Material mislabeled 2. Material not segregated	1	Raw material handling procedures Segregated storage Manufacturing Master Formula (MMF) Packaging Master Formula (PMF)	1	4	Acceptable
	b. Use of material that has not been inspected and released	Use of OOS raw material Adverse impact on product performance	4	1. Material not labeled 2. Material not segregated	1	Raw material handling procedures Segregated storage	1	4	Acceptable
Materials will be labeled in regard to lot identification, release status, and expiration date	c. Use of expired material	OOS product Deteriorated packaging material	3	1. Human error 2. Material not labeled properly	2	Raw material handling procedures Release tags with lot and expiration	1	6	Acceptable
						Incoming raw material inspection and testing			
						Raw materials are verified by two individuals at the time of use. The verification is documented within the device history file. In-process and finished product analysis			
						Raw material verification during batch production			
						Raw material verification during batch production			



Failure Mode and Effects Analysis
(Product/Process FMEA)

Item: Liquid Bicarbonate
Project: Liquid Bicarbonate
Prepared By: Brandi Heckman
FMEA Date (Orig): 3/12/07 (Rev.): 01 (5/15/07)

Process Responsibility: Haemotec, Inc. 383, Joseph-Carrier
Vaudreuil-Dorton, QC Canada J7V 5V5

Product/Process Function	Potential Failure Modes	Potential Effect(s) of Failure	S	Potential Cause / Mechanism of Failure	O	Current Process Control Preventions	D	RPN	Status
Finished Product/Production Process									
Must meet product specifications in regard to chemical concentration	a. Sodium and bicarbonate concentration OOS	Adverse impact on product and system performance. Adverse patient effects	4	1. Manufacturing error (human error and or equipment error) 2. Chemical contamination	1	Manufacturing procedures, employee training, and calibrated manufacturing equipment Product specifications and certificate of analysis	1	4	Acceptable
Must be free of bacterial contamination (<10cfu/ml)	a. Bacterial counts >10cfu/ml	Adverse impact on product and system performance. Adverse patient effects	4	1. Environmental contamination 2. Contaminated water used for manufacturing 3. Product Handling	2	RO/DI Water System Water quality monitoring HEPA Air Filtration PPE	1	8	Acceptable
Must be free of endotoxin (≤0.25EU/ml)	a. Endotoxin >0.25EU/ml	Fever response in patient	4	1. Contaminated water used for manufacturing	2	RO/DI Water System Water quality monitoring	1	8	Acceptable
pH must be between 7.5-8.5	a. pH OOS	Adverse impact on product and system performance.	3	1. Improper chemical composition	1	Product specifications Manufacturing procedures	1	3	Acceptable
Batch system sanitized daily	a. Residual sanitizer remains within the batching system	Chemical contamination of product	4	1. Human error 2. Inadequate rinse	2	Sanitization/rinse procedures	1	8	Acceptable

Failure Mode and Effects Analysis
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Process Responsibility: Haemotec, Inc. 383, Joseph-Carrier
 Vaudreuil-Dorion, QC Canada J7V 5V5

Product/Process Function	Potential Failure Modes	Potential Effect(s) of Failure	S	Potential Cause / Mechanism of Failure	O	Current Process Control Preventions	Current Process Control Detections	D	RPN	Status
Fabrication room must meet cleanliness standards prior to production	a. Untidy work environment	Contamination of product by debris	3	1. Dirty production area/equipment 2. Ineffective procedure 3. Contamination from equipment degradation	2	Housekeeping/cleaning procedures.	Verification of cleaning and documentation within MMF Visual inspection of in-process sample. Finished product analysis	1	6	Acceptable
Batch system must be rinsed free of previous batch	a. Residual chemical components remain from previous product	Chemical contamination of product	4	1. Human error 2. Inadequate rinse	2	Equipment cleaning procedures	Verification of cleaning and documentation within MMF Rise water analysis In-process and finished product analysis	1	8	Acceptable
Product is manufactured in accordance with MMF	a. Incorrect amount of raw materials added	OOS product	4	1. Inaccurate weight of dry raw material 2. Inaccurate volume purified water	2	Scales are calibrated, validated, and verified daily IQ/OQ/PQ on all tanks	Product analysis; in-process testing (batch adjustment) Finished product analysis.	1	8	Acceptable



Failure Mode and Effects Analysis
(Product/Process FMEA)

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 FMEA Date (Orig): 3/12/07 (Rev.): 01 (5/15/07)

Process Responsibility: Haemotec, Inc. 383, Joseph-Carrier
 Vaudreuil-Dorion, QC Canada J7V 5V5

Product/Process Function	Potential Failure Modes	Potential Effect(s) of Failure	S	Potential Cause / Mechanism of Failure	O	Current Process Control Preventions	Current Process Control Detections	D	RPN	Status
	b. Improper Mixing	Incomplete dissolution	4	1. Wrong valves open/closed 2. Mix time too short/water temperature 3. Improper flow rate/pressure 4. Raw material caking	1	Procedure verified/and documented during production. Validation production process Water system calibrated for temperature and pressure.	Visual inspection and in-process analysis. Finished product analysis	1	4	Acceptable
Production water must meet established purified water standards	c. Contaminated product water	Bacterial contamination of product and introduction of endotoxins	4	1. Water purification system failure	1	Water system with Endotoxin filters Validation UP005	Endotoxin and bioburden testing conducted on water samples taken daily. Finished product analysis	1	4	Acceptable
Packaging										
Packaging Materials must meet purchase specifications	a. Packaging materials of the wrong size and material	Packaging not compatible with production process Package failure in regard to adequate sealing and barrier to contamination	3	1. Improper vendor	1	Vendor qualification requirements Packaging purchase specifications	Incoming inspection and release of all packaging materials	1	3	Acceptable

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Failure Mode and Effects Analysis

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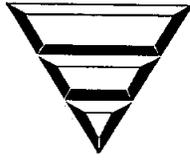
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Appendix 6



Fresenius Medical Care
North America

Dialysis Products Division

Design and Development Plan

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Appendix 8

AAMI RD61 STANDARD CHECKLIST

	RD-61 Standard Requirements	Liquid Sodium Bicarbonate Concentrate
<p>General (4.1.1)</p>	<p>General Labeling Requirements for Concentrates</p> <p>a) Name and address</p> <p>b) Date of Manufacture</p> <p>c) Lot/Batch No.</p> <p>d) Weight per container of each ingredient</p> <p>e) Batch systems volume of conc. water</p> <p>f) For proportioning systems, ratio of conc. & water to be mixed</p> <p>g) Trade name</p> <p>h) Statement for storage requirements</p> <p>i) Any special requirements</p> <p>j) Warning of bacterial growth in bicarbonate concentrate</p> <p>k) Statement to test the final conductivity and pH</p> <p>l) Statement to use water that meets ANSI/AAMI RD62:2001</p>	<p>a) Provided on label</p> <p>b) Provide expiration date</p> <p>c) Provided on label</p> <p>d) Provided on label as volume</p> <p>e) N/A since the product is not used in batch systems</p> <p>f) The label states the ratio of water to concentrate required for a particular machine.</p> <p>g) Provided on label</p> <p>h) Statement on label to avoid excessive temperature</p> <p>i) All instructions are listed on the label.</p> <p>j) Warning of bacterial growth in bicarbonate concentrate</p> <p>k) Statement provided on label</p> <p>l) Statement provided on label</p>
<p>4.1.2</p>	<p>Labeling requirements for liquid concentrate</p> <p>a) Expiration date of liquid concentrate</p> <p>b) Composition of the dialysate in mEq/L</p> <p>c) Statement that the solution is nonpyrogenic</p> <p>d) Fill volume of the container</p> <p>e) The dilutional effects on the final dialysate of any liquid spikes</p> <p>f) Nominal conductivity of the final dialysate when mixed using manufacturer's instructions</p>	<p>a) Provided on label</p> <p>b) Provided on label</p> <p>c) Provided on label</p> <p>d) Provided on label</p> <p>e) N/A</p> <p>f) Provided on label</p>

AAMI RD61 STANDARD CHECKLIST

4.1.3	Labeling requirements for powder concentrates	
	a) Conc. generators proportioning system or dialysis machine	a) N/A liquid concentrate
	b) Length of time conc. generator can expect to function	b) N/A liquid concentrate
	c) Amount of water required to reconstitute the concentrate	c) N/A liquid concentrate
	d) Time limit use on bicarbonate conc. to prevent bacteria	d) N/A liquid concentrate
4.1.4	e) Water quality that should be used to mix the conc.	
	Aqueous Concentrate	
	a) Label includes instructions on mixing thoroughly	a) Pre-mixed concentrate
4.1.5	b) Once opened, bicarbonate must be used with in a specific time	b) Provided on label
	c) Labels are provided to distinguish among solutions	
	Dry Concentrate	
	a) Label includes recommended storage conditions and mixing precautions	a) N/A liquid concentrate
	b) The numbers symbol should be easily visible and in the boundaries of the symbol	b) N/A liquid concentrate
	c) The container for proportioning systems shall display a geometric symbol	c) N/A liquid concentrate
4.1.6	d) Directions should instruct the user on proper use of the product, i.e. quality of water to be used, use of testing method to ensure proper dilution, any specific precautions	
	e) Labels should be a specific color per the type of product	e) N/A liquid concentrate
	f) Means should be provided to readily distinguish between dry concentrates and their ratios	
	g) Labels should be provided to readily distinguish between liquid concentrates and their ratios	

AAMI RD61 STANDARD CHECKLIST

4.2	Requirements for the concentrate	
4.2.1	Physical state	
	a) Concentrate for hemodialysis may be supplied in dry and/or aqueous form	a) This product is a liquid concentrate
4.2.2	Solute concentrations	
4.2.2.1	Liquid solute concentrations	
	a) All electrolytes shall be present within $\pm 5\%$ or $\pm 0.1 \text{ mEq/L}$ or greater except sodium, which shall be present within $\pm 2.5\%$.	a) Requirement of the manufacturing process and present on Certificates of Analysis
4.2.2.2	Powder Weights	
	a) When the concentrate is packaged in dry form and mixed according to manufacturer's instruction, the final concentrate shall meet 4.2.2.1	a) N/A liquid concentrate
4.2.3	Water Quality	
	a) Water quality used to manufacture the concentrate shall be in accordance with ANSI/AAMI RD62:2001	a) Statement provided on label
4.2.4	Bacteriology	
	a) Bicarbonate supplied as a liquid must be provided in a sealed container and must contain no more than 200CFU/mL at the end of its shelf life	a) QC requirements $\leq 10 \text{ CFU/mL}$
4.2.5	Fill Volume	
	a) Fill volumes of a liquid with batch systems shall be within 2%	a) N/A, product is not used with batch systems
	b) Nonbatch systems, fill is greater than 97% of stated volume	b) The volume produced is located on the label
4.2.6	PH	
	a) pH levels should meet the levels listed in the standard	a) pH between 7.5-8.5

AAMI RD61 STANDARD CHECKLIST

4.2.7	<p>Chemical grade</p> <p>a) All chemicals shall meet the requirements of the current USP-NF</p>	<p>a) All chemical used in the concentrate are purchased from approved vendors and are tested according to British Pharmacopeia (January 2007) methods or other validated test methods.</p>
4.2.8	<p>Particulates</p> <p>a) Dialysate concentrate shall be filtered through a 1.2 micron or finer particulate filter</p>	<p>a) At the time of manufacturing, during the filling process, the concentrate is filtered twice. Once through a 0.5µm and then a 0.2 µm filter.</p>
4.2.9	<p>Additives</p> <p>a) All ingredients in final concentrate shall be listed on the label</p>	<p>a) All ingredients are listed on the label</p>
4.2.10	<p>Containers</p> <p>a) Containers should not interact chemically or physically with their contents</p> <p>b) Each container shall be marked with the appropriate color and symbol to indicate its contents</p>	<p>a) The container material that contacts the liquid concentrate product is tested for biocompatibility and stability studies are performed.</p> <p>b) Each container is labeled accordingly to the standard</p>
4.2.11	<p>Pyrogenicity</p> <p>a) The concentrate shall be shown to be non-pyrogenic. If LAL is used, max. endotoxin shall not exceed 2 EU/mL</p>	<p>a) Product labeled non-pyrogenic and complies with standard. Endotoxin specification is ≤ 0.25 EU/mL</p>
4.2.12	<p>Bulk Delivered Concentrate</p> <p>a) When the concentrate is delivered in bulk form, a responsible person must comply with the contents of this section as described in RD61.</p>	<p>a) N/A - This section does not apply to the manufacture. It is not a bulk delivered concentrate.</p>

AAMI RD61 STANDARD CHECKLIST

4.2.13	Concentrate Generators	
	a) All applicable sections of this document dealing with powder are met	a) N/A liquid concentrate
	b) Container will function with the machine as defined by the manufacturer	b) N/A liquid concentrate
	c) Label shall clearly indicate the machines for which the concentrate generator is intended	c) N/A liquid concentrate
	d) Amount of time is indicated that the container can reasonably be expected to provide solution	d) N/A liquid concentrate
	e) Any additional information that the user might need to know	e) N/A liquid concentrate
4.3	Manufacturing Equipment	
	a) Any material components used in manufacturing shall not interfere with concentrate and alter the product	a) Surface contacts are in compliance with the standard.
5.0	Tests	
	a) Defines test methods to be used and mentions that other test methods may be used where validation of the test method is demonstrated	a) Tests are performed according to USP, but other validations are performed to ensure quality and/or compliance to the standard
5.1	Labeling and documentation requirements	
	a) Compliance with the labeling requirements of 4.1.1 can be determined by inspection	a) Compliance with this standard. Refer to Section 4.1.1.
5.2	Testing to meet the requirements for the concentrate	
5.2.1	Physical State	
	a) Concentrate supplied in aqueous or dry form	a) Compliance verified by visual inspection
5.2.2	Solute concentrations	
	a) Compliance with the requirements of 4.2.2 for NaHCO ₃ and NaCl.	a) Product complies with standards. Product is validated according to the appropriate test methods

AAMI RD61 STANDARD CHECKLIST

5.2.3	Water Quality	a) Use water in compliance with section 4.2.3 and ANSI/AAMI standards	a) Statement provided on label
5.2.4	Bacteriology	a) Concentrate containing bicarbonate supplied as a liquid must be provided in a sealed container and not contain more than 200 CFU/ml	a) Product labeled non-pyrogenic and complies with standard. Endotoxin specification is ≤ 0.25 EU/mL
5.2.5	Fill Volume	a) Fill volumes of a liquid with batch systems shall be within 2%	a) N/A, product is not used with batch systems
5.2.6	pH	b) Nonbatch systems, fill is greater than 97% of stated volume	b) The volume produced is located on the label. 4000 Series and 9000 Series Fill volume 6400mL (6420-6500mL) 8000mL (8020-8100mL)
5.2.7	Chemical Grade	a) Dialysate pH to be determined by appropriate dilution and then measuring pH with a glass electrode	a) Procedure performed at clinics.
5.2.8	Particulates	a) Purity of chemicals can be determined by test methods outlined in the USP	a) Design history files prove that USP methods or other validation procedures have been used to assure purity of the chemicals
5.2.8	Particulates	a) The concentrate shall be filtered through a 1.2 micron or finer particulate filter	a) At the time of manufacturing, during the filling process, the concentrate is filtered twice. Once through a 0.5 μ m and then a 0.2 μ m filter.

AAMI RD61 STANDARD CHECKLIST

5.2.9	Additives	a) Compliance with 4.2.9 (ingredients on label) can be determined by inspection of records. All ingredients in the final concentrate shall be listed on the label.	a) All ingredients are stated on the label
5.2.10	Containers	a) Tests for plastic containers	a) All packaging material in contact with product are minimally compliant to USP Class VI testing or FDA Part 177.
5.2.11	b) Compliance with 4.2.10 Pyrogenicity	a) Compliance with 4.2.11 determined by USP-NL or LAL test	b) See 4.2.10 a) Product is labeled non-pyrogenic and testing is performed in accordance with the standard.
5.3	Manufacturing Equipment	a) Biocompatibility of material components used in the manufacturing equipment should be verified	a) Complies to standard based on design control

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates
4000 Series
“Special” 510(k) Premarket Notification

Section VII: Labeling and Packaging

Line	Item	Label Text or Graphic as seen on the label
		81.25 g/L Sodium Bicarbonate
11	The fill volume of the container	Contents: 6.4 Liters (1.7 U.S. Gallons).
12	Storage requirements	Recommended Storage: Protect from Excessive Heat and Freezing
13	Warning	For use only with three-stream proportioning bicarbonate systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water that meets ANSI/AAMI RD62:2001.
14	Warning	Use with other equipment or without associated acid concentrate may cause patient injury or death.
15	Warning	Not for parenteral use
16	Warning of bacterial growth	Bacterial growth may occur in concentrated bicarbonate solutions. Avoid contamination.
17	Warning	Federal (USA) law restricts this device to sale by or on order of a physician.
18	Warning	Do not use if packaging is damaged or seal is broken.
19	Country of origin	Made in Canada
20	Label part number and rev date	Label part number and revision date
21	Customer Service Number	For US call 1-800-323-5188 For Canada 1-877-633-0013

Copies of the predicate device labeling are provided in **Appendix 10– Labeling**.

Appendix 9

Appendix 10

Dialysis Products Division

GRAPHICS SHEET

GRAPHICS DESCRIPTION: Naturalyte Carton Label – 08-4400-1				REF. DOC.: PK-150
APPROVED BY: ECO # 19823	PREPARED BY: J. Ball	DATE: 01/31/07	VERIFIED BY: R. Marchand	DATE: 03/08/07

THIS SPECIFICATION AND/OR THE SUBJECT MATTER IS RESTRICTED SOLELY FOR THE USE OF FMENA AND FMENA VENDOR PROCUREMENT.

APPROVED GRAPHICS

S54786
S54786
QT2-2810

1 2

DG
PPC

Dry Pack For Bicarbonate Dialysis

NaturaLyte® 4000

CATALOG NO. 08-4400-1

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

Ionic Contribution of Bicarbonate Concentrate:
(Nominal dilution 1:1.72:42.28)

Sodium Bicarbonate	37 mEq/L
Bicarbonate	37 mEq/L

Chemical Composition:
650 gm. Sodium Bicarbonate, U.S.P.
Dissolved 81.25 g/l

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

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

DIRECTIONS FOR USE

One carton of NaturaLyte 4000, when used in conjunction with NaturaLyte 4000 Series acid formulation, will produce enough dialyzing fluid for approximately 7 hours at a maximum flow rate of 500 ml/min. NaturaLyte 4000 dry pack, when mixed according to directions, produces 8 liters or 2.1 gallons of bicarbonate base concentrate.

DO NOT USE IF PACKAGING IS DAMAGED OR PACKAGE SEAL IS BROKEN. RECOMMENDED STORAGE: PROTECT FROM EXCESSIVE HEAT AND FREEZING.

- To mix the NaturaLyte 4000 dry pack, add purified water to the container provided with the dialysis machine. Fill to the 7.7 liter mark.
- Container must be free of bacterial and chemical contamination (AAMI RDS). Use purified water that meets or exceeds AAMI hemodialysis water quality standards (RDS). Water temperature should be 24°C ± 2°C.
- Empty the entire NaturaLyte 4000 dry pack into the water and cap the container.
- Gently agitate the container a sufficient number of times to dissolve the powder. **NOTE:** Vigorous mixing and propeller style mixers can drive carbon dioxide from the solution and are therefore not recommended.
- Refer to the directions for use provided in the dialysis machine operator's manual to ensure proper set up. Check conductivity and pH of dialyzing fluid before starting treatment and each time solution is added (AAMI RDS).

NOTE: This bicarbonate base concentrate should be used on the same day it is mixed. Storage in a closed container is recommended to minimize CO₂ loss and resulting precipitation in dialysis equipment.

70-0950.05 02/07

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

Ionic Contribution of Bicarbonate Concentrate:
(Nominal dilution 1:1.72:42.28)

Sodium Bicarbonate	37 mEq/L
Bicarbonate	37 mEq/L

Chemical Composition:
650 gm. Sodium Bicarbonate, U.S.P.
Dissolved 81.25 g/l

Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

1 2

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

Subject: 510(k) Number K071387

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/A

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 876-5820

Review: Carolyn Y Newland GRDB 6/14/07
(Branch Chief) (Branch Code) (Date)

Final Review: Herbert Pomeroy 6/16/07
(Division Director) (Date)

Internal Administrative Form K071387

	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 #191-2 and Federal Register 90N0332, September 10, 1991.		

K071387

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

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

Device Trade Name: Fresenius Naturalyte Sodium Bicarbonate Liquid Concentrates 4000 Series
510(k) Number: K071387

Common Name: dialysate concentrate for hemodialysis - Liquid

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 Dry Pack Bicarbonate Concentrate (Biosol Powder Bicarbonate Concentrates) (K981043).

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

Explanations to the Preceding Checklist:

NARRATIVE DEVICE DESCRIPTION

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

C. Neuland
6/14/07

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE RE: **K071387– Fresenius – Naturalyte Liquid Acid Concentrate**

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

Fresenius Naturalyte Dry Pack Bicarbonate Concentrate (Biosol Powder Bicarbonate Concentrates) (K981043) and Fresenius Naturalyte® Granuflo® Dry Acid Concentrate (K030497).

2. Submitter's statement that the indication/ intended use of the modified device as described in its labeling has not changed along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

The originally sent-in indication for use is: Bicarbonate concentrate for Bicarbonate Dialysis."

The predicate's Dry Bicarbonate indication is "This concentrate is formulated to be used with a three stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates."

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

These indications are essentially the same, but not identical as is required for a Special 510(k). I spoke with Janet Kay and she said that they did not have a formal indication for use for the K981043. I pointed out that I had the form in front of me. She agreed that the indication for the proposed device could be the same. She sent the modified indication for use form and the 510(k) Summary.

The new indication for use is:

This concentrate is formulated to be used with a three stream hemodialysis machine which is calibrated for acid and bicarbonate concentrates.

The indications for use are present and are now acceptable.

3. A description of the device modifications including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the fundamental scientific technology of the modified device has not changed.

(b) (5)

(b)(5)

(b) (4)

(b)(4)

4. Comparison Information (similarities and differences) to applicant's legally marketed predicate device include labeling, intended use, physical characteristics, and materials.

Labeling: The labeling includes the following:

Naturalyte® 4000 Sodium Bicarbonate Liquid Concentrate

Table VI - 1

Line	Item	Label Text or Graphic as seen on the label
1	Labels color	BLUE triangle
2	Use geometric shapes required by RD61	'BLUE' Triangle 45X
3	Manufacture's name address	FMCNA 920 Winter Street, Waltham MA, 02451 1-800-323-5188
4	Device Name	Naturalyte® Sodium Bicarbonate Liquid Concentrate
5	Catalogue number	08-4000-LB (U.S.) 1B-101 (Canada) with Barcode
6	Lot number	Yes, shown as MONTH/2007 12 months from date of manufacturer
7	Directions for Use	Use in accordance with machine operating instructions Check conductivity and pH of dialyzing fluid before starting treatment and each time solution is added (AAMI RD 52) Check for precipitate. Use only if precipitate can be completely dissolved. Once this product is opened, the bicarbonate concentrate must be used within 24 hours. Storage in a closed container is recommended to minimize CO2 loss and resulting precipitation in dialysis equipment. Product must be used before the end of the expiration month (EXP DATE) on this label.
8	Expiration date and format:	Yes, shown as 'mm/yyyy'. Shelf life is 12 months from date of manufacturer.
9	Pyrogen claim	Solution in an un-opened container is non-pyrogenic.
10	Chemical composition	Ionic Contribution of Bicarbonate Concentrate to final dialysate: (Nominal dilution 1:1.72-42.23) Na 37mEq/L HCO ₃ 37mEq/L Chemical Composition

Line	Item	Label Text or Graphic as seen on the label
		81.25 g/L Sodium Bicarbonate
11	The fill volume of the container	Contents: 6.4 Liters (1.7 U.S. Gallons)
12	Storage requirements	Recommended Storage: Protect from Excessive Heat and Freezing
13	Warning	For use only with three-stream proportioning bicarbonate systems when calibrated to proportion 1 part acid to 44 parts bicarbonate base and water that meets ANSI/AAMI RD62:2001
14	Warning	Use with other equipment or without associated acid concentrate may cause patient injury or death.
15	Warning	Not for parenteral use
16	Warning of bacterial growth	Bacterial growth may occur in concentrated bicarbonate solutions. Avoid contamination.
17	Warning	Federal (USA) law restricts this device to sale by or on order of a physician.
18	Warning	Do not use if packaging is damaged or seal is broken
19	Country of origin	Made in Canada
20	Label part number and rev date	Label part number and revision date
21	Customer Service Number	For US call 1-800-323-5188 For Canada 1-877-633-0013

The color and symbol labeling meets AAMI requirements. The expiration date is 12 months, which is adequate based on the 17 month testing.

5. A Design Control Activities Summary which includes:
 - a) Identification of Risk Analysis method used to assess the impact of the modification on the device and its components, and the results of the analysis:

(b) (4)

(b)(4)

- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Testing includes: (b) (4) (b)(4)

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

- c) A declaration of conformity with design controls. The declaration of conformity includes:
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

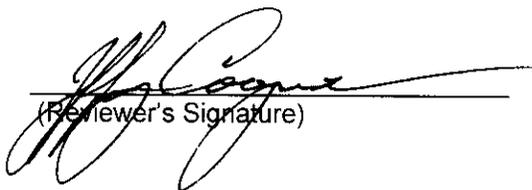
These are signed.

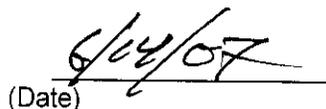
6. A Truthful and Accurate Statement, a 510(k) Summary, and the Indications for Use Enclosure.

These are enclosed.

Recommendation:

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, the firm claims the device to be substantially equivalent to the previously cleared device.


(Reviewer's Signature)


(Date)

C Neerland
6/14/07

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

510(k) Number: K071387 – Fresenius Naturallyte Dry Pack Bicarbonate Concentrate (Biosol Powder Bicarbonate Concentrates) (K981043).

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.	✓	Were different, but are now corrected to the same.
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.		

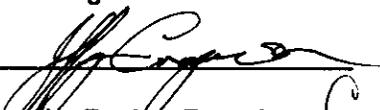
- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

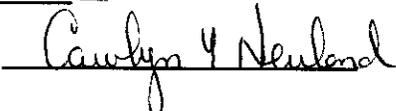
Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

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

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening: YES

Reviewer: 

Concurrence by Review Branch: 

Date: 6/8/07

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to 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>

K030497



Fresenius Medical Care

Indications for Use Statement

Device Name:

Fresenius Naturalyte® Granuflo® Dry Acid Concentrate

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Fresenius Medical Care North America

Corporate Headquarters: 95 Hayden Avenue, Lexington, MA 02420 (781) 432-4000

0800000

45

17

510(k) Number (if known): K981043

Device Name: DIALYSATE ACID CONCENTRATE (LIQUID & POWDER)

Indications For Use:

THIS CONCENTRATE IS FORMULATED TO BE USED WITH
A THREE STREAM HEMODIALYSIS MACHINE WHICH IS
CALIBRATED FOR ACID AND BICARBONATE CONCENTRATES.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

18

510(k) Number (if known): K981043

Device Name: DIALYSATE BICARBONATE CONCENTRATE (LIQUID & POWDER)

Indications For Use:

THIS CONCENTRATE IS FORMULATED TO BE USED WITH
A THREE STREAM HEMODIALYSIS MACHINE WHICH IS
CALIBRATED FOR ACID AND BICARBONATE CONCENTRATES.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

MA

19

510(k) Number (if known): K981043

Device Name: DIALYSATE ACETATE CONCENTRATE (LIQUID & POWDER)

Indications For Use:

THIS CONCENTRATE IS FORMULATED TO BE USED WITH
A TWO STREAM HEMODIALYSIS MACHINE CALIBRATED
TO AN ACETATE CONCENTRATED DILUTION RATIO OF 1:34.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

210 20



Fresenius Medical Care

Indications for Use

510(k) Number (if known): K071387

Device Name:

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates, 4000 Series.

Indications for Use:

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

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

21



Fresenius Medical Care

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate "Special" 510(k) Premarket Notification

510(k) Summary

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: June 14, 2007

B. Device Name:

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



Fresenius Medical Care

Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrate "Special" 510(k) Premarket Notification

510(k) Summary

C. Predicate Device Name:

The Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrate is a modified version of the Fresenius Biosol Powder Bicarbonate Concentrate

- #K981043 (5/26/1998)

D. Device Description/Indications for Use:

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

Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

E. Substantial Equivalence:

Substantial Equivalence Decision Making Process

1. Is the product a device?

YES - The Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrate is 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 device is equivalent to the unmodified device.

Fresenius modified Fresenius Naturallyte® Sodium Bicarbonate Liquid Concentrates - Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates

Fresenius unmodified Biosol Powder Bicarbonate Concentrate - Intended Use

This concentrate is formulated to be used with a three steam hemodialysis machine which is calibrated for acid and bicarbonate concentrates



Fresenius Medical Care

Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrate “Special” 510(k) Premarket Notification

510(k) Summary

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

NO – The Fresenius Naturalyte® Sodium Bicarbonate Liquid Concentrates is a modified versions of the Biosol Powder Bicarbonate 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® Sodium Bicarbonate Liquid Concentrate and demonstrates that it is substantially equivalent to the unmodified devices.

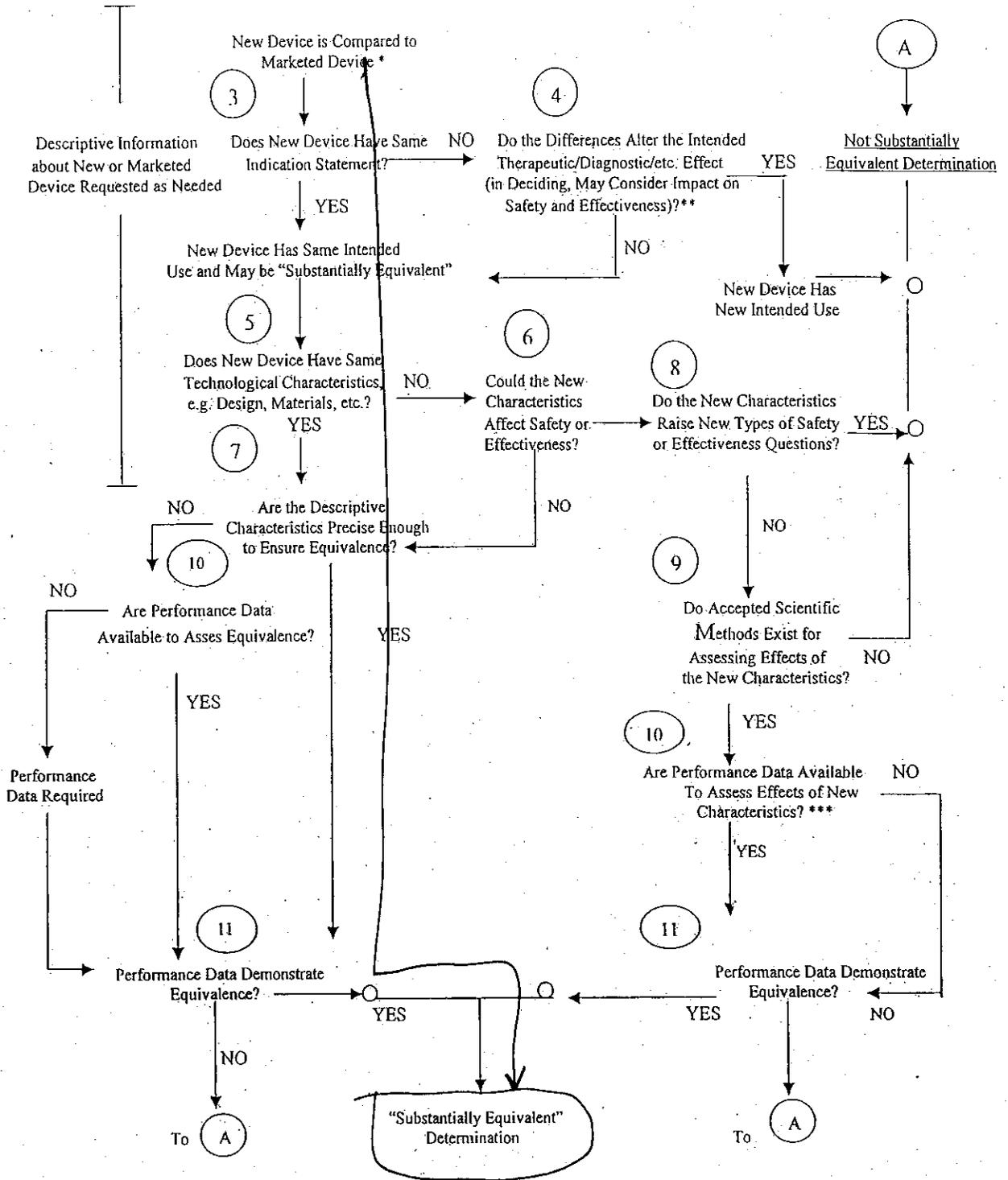
F. Safety Summary

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrate is substantially equivalent in chemical formulation, chemical composition, and intended use to the commercially available Biosol Powder Bicarbonate Concentrates currently distributed as Fresenius Naturalyte® Dry Pack Bicarbonate Concentrates. In addition, testing of the modified device indicates that the formulations are safe and effective for its intended use.

G. General Safety and Effectiveness Concerns

The Fresenius modified Naturalyte® Sodium Bicarbonate Liquid Concentrates are to be used with a three-stream proportioning systems when calibrated to specified proportions depending on the series and mixed with water that meet ANSI/AAMI RD 62.. Use with other equipment or without associated bicarbonate concentrate may cause patient injury or death. Not for Parenteral Use.

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.