



USER: JOHNSON, SHEVON E (sxj)

FOLDER: K053120 - 143 pages (FOI:09007009)

COMPANY: EXCELSIOR MEDICAL CORP.
(EXCEMEDIA)

PRODUCT: CATHETER, INTRAVASCULAR,
THERAPEUTIC, SHORT-TERM LESS THAN
30 DAYS (FOZ)

SUMMARY: Product: STERILE FIELD SALINE AND
HEPARIN LOCK FLUSH SYRINGES

DATE REQUESTED: Tue Jan 18 24:00:00 2011

DATE PRINTED: Fri Feb 11 09:32:16 2011

Note: Releasable Version

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DEC 9 2005

K053120

510(k) SUMMARY

Submitted by:

Ruben Martinez
Director, Regulatory/Quality
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 97753

Proposed Device:

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes

Predicate Device:

Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Device Description and Statement of Intended Use:

The modification which is the subject of this Special 510(k) is substitution of the current dust cover packaging with Sterile Field packaging. All other aspects of the product design remain unchanged.

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes are intended for flushing IV catheters and IV tubing. This is the same intended use previously cleared for the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes.

Summary of Technological Characteristics of New Device to Predicate Device

The technological characteristics of Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes do not differ from the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes. The devices use the same fundamental scientific technology and have the same intended use.

Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Mr. Ruben Martinez
Director Regulatory/Quality
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, New Jersey 07753

Re: K053120
Trade/Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 28, 2005
Received: November 30, 2005

Dear Mr. Martinez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use Statement

510(k) Number (if known): K053120

Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Indications For Use:

Excelsior Sterile Field Saline Flush Syringes and Heparin Lock Flush Syringes are indicated for use in flushing IV catheters and IV tubing.

John H. Murphy MD 12/2/05
Anesthesiology, General Hospital,
Device Control, Dental Devices
Number K 053120

Prescription Use _____ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Mr. Ruben Martinez
Director Regulatory/Quality
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, New Jersey 07753

Re: K053120

Trade/Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 28, 2005
Received: November 30, 2005

Dear Mr. Martinez:

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.

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Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use Statement

510(k) Number (if known): K053120

Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Indications For Use:

Excelsior Sterile Field Saline Flush Syringes and Heparin Lock Flush Syringes are indicated for use in flushing IV catheters and IV tubing.

Shah K. Murthy MD 12/2/15
Director of Anesthesiology, General Hospital,
Infection Control, Dental Devices
Number: K053120

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

November 23, 2005

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

EXCELSIOR MEDICAL CORP.
1923 HECK AVE.
NEPTUNE, NJ 07753
ATTN: RUBEN MARTINEZ

510(k) Number: K053120
Product: STERILE FIELD
SALINE AND
HEPARIN LOCK
FLUSH SYRINGES

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified 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>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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

November 07, 2005

EXCELSIOR MEDICAL CORP.
1923 HECK AVE.
NEPTUNE, NJ 07753
ATTN: RUBEN MARTINEZ

510(k) Number: K053120
Received: 07-NOV-2005
Product: STERILE FIELD SALINE
AND HEPARIN LOCK
FLUSH SYRINGES

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a 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. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/oivd/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmmain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation

K053120

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6023190-956733 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) EXCELSIOR MEDICAL 1923 Heck Avenue Neptune NJ 07753 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 201108098		2. CONTACT NAME Ruben Martinez 2.1 E-MAIL ADDRESS rmartinez@excelsiormedical.com 2.2 TELEPHONE NUMBER (include Area code) 732-776-7525 4100 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 732-776-7600	
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 (FOR FISCAL YEAR 2005) \$3,833.00			27-Oct-2005

Form FDA 8601 (08/2003)

Close Window

Handwritten initials and date: 10/27/2005

SPECIAL 510(k): DEVICE MODIFICATION

**Modification to Sterile Saline and Heparin Lock Flush
Syringes**

**Excelsior Medical Corporation
1923 Heck Avenue
Neptune, New Jersey 07753**

November 4, 2005

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CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 11/04/2005	User Fee Payment ID Number MD6023190-956733	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> 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 EXCELSIOR MEDICAL CORPORATION		Establishment Registration Number (if known) 2027791	
Division Name (if applicable)		Phone Number (including area code) (732) 776-7525	
Street Address 1923 HECK AVENUE		FAX Number (including area code) (732) 776-7600	
City NEPTUNE	State / Province NEW JERSEY	ZIP/Postal Code 07753	Country USA
Contact Name RUBEN MARTINEZ			
Contact Title DIRECTOR REGULATORY/QUALITY		Contact E-mail Address rmartinez@excelsiormedical.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>):		

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
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Line extension		

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 <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	2	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)		
510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K962938	1 Sterile Saline Flush Syringe	1 Excelsior Medical Corporation
2 K023749	2 Heparin Lock Flush Syringe	2 Excelsior Medical Corporation
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 21 CFR 880.5200 Catheter, Intravascular, k Therapeutic, Short-Term, Less Than 30 Days

Trade or Proprietary or Model Name for This Device	Model Number
1 Sterile Field Saline Flush Syringe	1
2 Sterile Field Heparin Lock Flush Syringe	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1 K962938	2 K023749	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 FOZ	C.F.R. Section (if applicable) 880.5200	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)
 For use in flushing IV catheters and IV tubing.

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 2027791		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name EXCELSIOR MEDICAL CORPORATION			Establishment Registration Number 2027791		
Division Name (if applicable)			Phone Number (including area code) (732) 776-7525		
Street Address 1923 HECK AVENUE			FAX Number (including area code) (732) 776-7600		
City NEPTUNE		State / Province NEW JERSEY	ZIP/Postal Code 07753	Country USA	
Contact Name RUBEN MARTINEZ		Contact Title DIRECTOR REGULATORY/QUALITY		Contact E-mail Address rmartinez@excelsiormedical.com	

<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	

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

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

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

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

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



November 4, 2005

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

RE: Special 510(k): Device Modification

**Modification to K962938 Sterile Saline and K023740
Heparin Lock Flush Syringes cleared October 25, 1996
and May 13, 2003, Respectively**

Dear Colleague:

This is to notify you of the intent of Excelsior Medical Corporation to market Sterile Saline and Heparin Lock Flush Syringes in Sterile Field packaging as a line extension to Excelsior's currently marketed Sterile Saline and Heparin Lock Flush Syringes. The Sterile Field Saline and Heparin Lock Flush Syringes represent a modification to the current Sterile Saline and Heparin Lock Flush Syringes, cleared under K962938 and K023749, on October 25, 1996, and May 13, 2003, respectively,

Common/Usual Name: Saline flush syringe and heparin lock flush syringe

**Manufacturer/Sterilizer's Name, Site, Address and
Establishment Registration Number:**

Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 07753
Establishment registration # 2027791

**Owner/Operator (firm headquarters) Address and
Establishment Registration Number:**

Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 07753
Establishment registration # 2027791

Classification Name: Catheter, Intravascular, Therapeutic, Short-
Term Less Than 30 days

Classification Product Code: FOZ

Classification: Class II in 21 CFR § 880.5200

Predicate Device Information:

Excelsior Saline Flush Syringe cleared under K962938 on
October 25, 1996
Excelsior Heparin Lock Flush Syringe cleared under K023740
on
May 13, 2003

Labeling:

The proposed labeling for the Sterile Field Saline Flush and
Sterile Field Heparin Lock Flush is identical to the labeling for
the predicate devices except for additional information on use of
the sterile field packaging. A copy of the proposed labeling is
provided in **Attachment 1**. Labeling for the predicate devices is
provided in **Attachment 2**.

Intended Use:

The Sterile Field Saline Flush and Sterile Field Heparin Lock
Flush syringes are intended for use in flushing IV catheters and
IV tubing. This is the same intended use previously cleared for
the currently marketed devices. An Indications for Use
Statement is provided in **Attachment 3**.

Device Description and Comparison:

The modification which is the subject of this Special 510(k) is replacement of the existing "dust cover" packaging for Sterile Saline and Heparin Lock Flush Syringes with packaging that acts as a sterile barrier. This allows the exterior surfaces of the syringes as well as the fluid path to be sterile as long as the packaging is not opened. All other aspects of the flush syringes are unchanged.

The Saline Flush Syringes and Heparin Lock Flush syringes are intended for use flushing IV catheters and IV tubing. The proposed modification does not affect the intended use of the device and does not alter the fundamental scientific technology of the device. As such, Excelsior believes that the modification is suitable for a "Special 510(k)" submission.

A descriptive comparison of common features and the key difference of the modified device to the predicate device is provided below.

Common Features:

The common features of the proposed Sterile Field Saline and Heparin Lock Flush Syringes and the current Sterile Saline and Heparin Lock Flush Syringes are described below:

1. Same intended use

As described in the Indications for Use Statement in **Attachment 3**, the proposed and current flush syringes have the same intended use.

2. Same operating principle

There are no changes proposed to the flush syringes except for substitution of the dust cover with the sterile field packaging. The operating principle of the syringes remains unchanged.

3. Same fundamental scientific technology (mechanical principle)

The proposed and current flush syringes use the same fundamental scientific technology.

4. Same flush solutions prefilled in syringes

Both the predicate and the modified syringes contain the same solutions, i.e. 0.9% sodium chloride solution and heparin lock flush solution, 10 units per mL or 100 units per mL.

5. Same materials

Both the predicate devices and the modified syringes contain the same materials, except for the sterile field packaging.

6. Same sterilization process

Both the predicate and the modified syringes are (b) (4)

Key Difference:

As indicated in **Common Features**, there are no changes proposed to the flush syringes except for the sterile field packaging. The Chevron pouch is a two-part envelope, made with one part 3.3 mil white Surgical Kraft paper and one part 1.75 mil clear PP/PET laminate. The Kraft paper contains printed information.

Substantial Equivalence:

Excelsior believes the proposed Sterile Field Saline and Heparin Lock Flush syringes are substantially equivalent, for purposes of Section 510(k) of the Federal Food, Drug and Cosmetic Act only, to the current Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes, cleared under premarket notification K962938 on October 25, 1996 and K023740 on May 13, 2003, respectively. The modified flush syringes have the following similarities to the predicate Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes:

- Same indicated use
- Same operating principle
- Same design of syringe
- Same solutions, i.e. 0.9% sodium chloride solution and heparin lock flush solution, either 10 units per mL or 100 units per mL

- Same materials
- Same sterilization processes

Summary of Design Control Activities:

Excelsior has cleared 510(k)s for the two predicate devices. Design verification testing was performed by Excelsior which included functional, material biocompatibility, and microbial challenge testing. Excelsior's design control activities focused on the verification tests applicable to the sterile field packaging and the sterilization cycle exposure time parameter required to verify a Sterility Assurance Level of 10^{-6} .

The risk analysis methods used to assess the impact of the modifications were analysis of the stability and sterility of the modified device. These verification tests were performed to ensure the modified device is as safe and effective as the predicate device. The modified device met all acceptable criteria. A list of the design verification tests performed follows:

Verification Tests

Modification	Test Performed	Acceptance Criteria
Sterile Field Packaging	(b) (4)	
Sterile Field Packaging		

510(k) Summary:

A 510(k) summary for the proposed Sterile Field Flush syringes is provided in **Attachment 5**.

Truthful and Accuracy Certification

A certification statement as required by 21 CFR § 807.87(k) is provided in **Attachment 6**.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S. C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for review of our application. If you have any questions regarding this submission, please contact me.

Sincerely,



Ruben Martinez
Director, Regulatory/Quality
(732) 776-7525 telephone
(732) 776-7600 (Fax)
rmartinez@excelsiormedical.com

Attachments

Attachment 1

PROPOSED LABELING

Sterile Field Saline Flush

Quantity 2

Syrex 10mL 0.9% Sodium Chloride Injection USP

♦ Latex Free ♦ Preservative Free

♦ Contents of Package may be dropped on Sterile Field

Instructions for use

Contents Sterile, Non-pyrogenic in unopened and undamaged package. Use Aseptically – For IV Flush Only. Follow CDC guidelines and your institution's procedures for IV administrations.

1. Inspect package integrity including protective wrapping, syringe and tip cap. Do not use if packaging is damaged, syringe is leaking or tip cap is missing or not fully attached to syringe.
2. Remove syringes from package. Contents of package may be dropped on sterile field.
3. Visually inspect the syringe and solution. Do not use if solution contains a precipitate, particulate matter or is discolored, cloudy or hazy.
4. Remove tip cap from end of syringe.
5. Attach blunt cannula or needle if required.
6. Hold syringe with tip upward, tap side for bubbles to rise, apply and maintain pressure to plunger until all air is expelled from the syringe (and needle or blunt cannula if attached).
7. Use in accordance with any warnings or precautions appropriate to the medications being administered. Do not use if compatibility is in doubt.
8. Administer through the appropriate site a quantity of solution for maintaining the patency of the indwelling venous access device, in accordance with an appropriate protocol or the recommendation of the manufacturer of the venous access device.
9. Rx Only. Each syringe for Single Use Only- Discard syringe and any unused portion of the solution.

Store at Controlled Room Temperature (15 - 30°C).

Protect from Freezing.

Sterile Field Saline Flush

Syrex Neptune, NJ

(800) 487-4276

(b) (4) 10mL SFF

(b) (4)

Box Label

- 1. External lot number used, ending in 9D
- 2. Expiration: (b) (4)
- 3. List number E0100-20
- 4. Barcode present on label
- 5. Qty 30 Sterile Field Saline Flush
- 6. Tolerance (-.5/+1 mL)

Master Label

- 12. Top of label says 10 mL Sterile Field Flush
- 13. 8 Boxes of 30 (2 per/pkg)
- 14. List: E0100-20
- 15. External lot number is used, ending in 9D
- 16. Expiration: (b) (4)
- 17. Label is white

Pouch Label

- 7. List: E0100-20
- 8. External lot number used, ending in 9D
- 9. Expiration: (b) (4)
- 10. Bar code on right hand side
- 11. "Push on plunger with tipcap attached to break seal" at bottom

List: E0100-20
Lot: 19-019-9D
Exp: 1 SEP 2007



Push on plunger with tipcap attached to break seal.

Inner box type: 10 mL Inner

Master box type: Master 10 mL

Qty 30 Sterile Field Saline Flush (two 10mL Syringes/package)

Contents sterile. **Contents of package may be dropped on Sterile Field.** Each unopened and undamaged package, contains two 10mL (-0/+1mL) syringes of a sterile, pyrogen-free isotonic solution of 0.9% Sodium Chloride Injection USP, with an osmolarity of 0.31mOsmol/mL, pH 4.5 – 7.0. Pharmacology: 0.9% Sodium Chloride Injection USP is a sterile aqueous injection having approximately the same osmotic pressure and composition as extracellular fluids. It is non-irritating to tissues. Indications and Usage: For use as a sterile isotonic vehicle for IV flush only. Contraindications: Hypernatremia and fluid retention, when the administration of sodium or chloride could be clinically detrimental. Precautions: If compatibility is in doubt, consult the appropriate specialized literature. **Do not use if solution is discolored or contains a precipitate.** Administration: This product should be **inspected visually for particulate matter and discoloration prior to use.** Caution: Federal (USA) law prohibits dispensing this device without prescription. Store at controlled room temperature (15°C - 30°C). **Do not freeze.** Use Aseptically – For IV Flush Only. Follow CDC guidelines and your institution's procedures for IV administrations. See Instructions for use on each package.

**Latex Free
Preservative Free**

**List: E0100-20
Lot: 19-019-9D
Exp. 1 SEP 2007**

**Made in USA
(800) 487-4276
Syrex Neptune, NJ**



0110363807100203

**10mL STERILE FIELD FLUSH
8 BOXES OF 30 (2 PER/PKG)**

**List: E0100-20
Lot: 19-019-9D
Exp. 1 SEP 2007**



0120063807100200

17
99

Alliance 10mL SFF
NDC # 01203 63807 10092

Box Label

1. External lot number used, ending in AA
2. Expiration: (b) (4)
3. Order number 10092
4. Qty 30 Sterile Field Saline Flush
5. Tolerance (-.5/+1 mL)

Master Label

10. External lot number is used, ending in AA
11. Expiration: (b) (4)
12. Sterile Field Flush Order #10092
13. 8 Boxes of 30pkg, 2 per/pkg
14. Label is pink

Pouch Label

6. External lot number used, ending in AA
7. Expiration: (b) (4)
8. Order # 10092
9. "Push on plunger with tipcap attached to break seal" at bottom

**Lot 36-006-AA
EXP 09-01-07
Order # 10092**

**Push on plunger with tipcap
attached to break seal.**

Inner box type: Brown 10 mL Inner

Master box type: Master 10 mL

Qty 30 Sterile Field Saline Flush (two 10mL Syringes/package)

Contents sterile. **Contents of package may be dropped on Sterile Field.** Each unopened and undamaged package, contains two 10mL (-0/+1mL) syringes of a sterile, pyrogen-free isotonic solution of 0.9% Sodium Chloride Injection USP, with an osmolarity of 0.31mOsm/L, pH 4.5 – 7.0. **Pharmacology:** 0.9% Sodium Chloride Injection USP is a sterile aqueous injection having approximately the same osmotic pressure and composition as extracellular fluids. It is non-irritating to tissues. **Indications and Usage:** For use as a sterile isotonic vehicle for IV flush only. **Contraindications:** Hyponatremia and fluid retention, when the administration of sodium or chloride could be clinically detrimental. **Precautions:** If compatibility is in doubt, consult the appropriate specialized literature. **Do not use if solution is discolored or contains a precipitate.** **Administration:** This product should be **inspected visually for particulate matter and discoloration prior to use.** **Caution:** Federal (USA) law prohibits dispensing this device without prescription. Store at controlled room temperature (15°C - 30°C). **Do not freeze.** Use Aseptically – For IV Flush Only. Follow CDC guidelines and your institution's procedures for IV administrations. See Instructions for use on each package.

Lot 36-006-AA EXP 09-01-07
Sterile Field Flush Order # 10092
8 Boxes of 30pkg, 2 per pkg
STORE AT CONTROLLED ROOM TEMPERATURE
15°C TO 30°C

**Latex Free
Preservative Free**
(b) (4)

**Exp. 09-01-07
Lot 36-006-AA
Order # 10092**

**Made in USA
(800) 487-4276
Syrex Neptune, NJ**

18

100

Attachment 2

PREDICATE DEVICE LABELING

(b) (4) / Syrex 5mL 10 Unit
Film barcode # 50005

Box Label

1. External lot number used. ending in BB
2. Expiration: (b) (4)
3. Item # 513602
4. (b) (4)
5. Qty 100 is not too close to top edge
6. Top of label says Syrex 5 mL – Heparin Lock Flush Solution. 10 Units/mL.
7. Label is blue

Inner box type: 5/12 Inner
(1 bundle packages 75,000 syringes)

Master Label

8. External lot number top left and bottom right. -BB
9. Expiration: (b) (4)
10. Item # 513602
11. 10 BOXES OF 100 SYRINGES
12. QTY. 1,000 SYRINGES
13. Text is not cut off on left, right, top or bottom edge
14. Label is blue

Master box type: 5/12 Outer
(1 bundle packages 125,000 syringes)

102
20

Qty. 100

Syrex 5mL – Heparin Lock Flush Solution, 10 Units/mL

For IV Flush Only For Single Use Only

- Store at 20°-25°C (68°-77°F); excursions permitted to 15°- 30°C (59°-86°F). Protect from freezing.
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- **Push on plunger with tipcap attached to break seal.**
- See package insert for additional information.

Recommendation:

A slower administration rate is recommended to minimize a possible unpleasant taste some patients may experience.

Made in USA
Syrex, LLC
Neptune, NJ
(800) 487-4276
Item # 513602

Latex Free
Preservative Free
Terminally Sterilized
Exp. 02-01-07 Lot# 22-008-BB
(b) (4)

LOT # 22-008-BB Exp. Date: 02-01-07
10 BOXES OF 100
QTY. 1,000 SYRINGES
Store at 20°-25°C (68°-77°F)
ORDER #513602 22-008-BB

Heparin Lock Flush Solution, USP 10 Units/mL
Heparin Lock Flush Solution, USP 100 Units/mL

For IV Flush Only For Single Use Only

INDICATIONS FOR USE:

To maintain patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely flush the vascular access device with Heparin Lock Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy.

PRODUCT DESCRIPTION:

Each unopened and undamaged polypropylene latex-free luerlock syringe contains the labeled volume of a sterile, pyrogen-free solution of Heparin Lock Flush Solution, USP derived from porcine intestinal mucosa in 0.9% sodium chloride USP with a pH range of 5.0 - 7.5.

Heparin is a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1) α -L-iduronic acid 2-sulfate, (2)2-deoxy-2-sulfamino- α -D-glucose 6-sulfate, (3) β -D-glucuronic acid, (4)2-acetamido-2-deoxy- α -D-glucose, and (5) α -L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2)>(1)>(4)>(3)>(5), and are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is strongly acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions.

CLINICAL PHARMACOLOGY:

Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*. Heparin acts at multiple sites in the normal coagulation system. Small amount of heparin, in combination with anti-thrombin III (heparin cofactor), can inhibit thrombosis by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin. Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inactivating thrombin and preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor.

Bleeding time is usually unaffected by heparin. Clotting time is prolonged by full therapeutic doses of heparin; in most cases, it is not measurably affected by low doses of heparin. Peak plasma levels of heparin are achieved 2 to 4 hours following subcutaneous administration, although there are considerable individual variations. Loglinear plots of heparin plasma concentration with time, for a wide range of dose levels, are linear which suggests the absence of zero order processes. Liver and the reticulo-endothelial system are the sites of biotransformation. The biphasic elimination curve, a rapidly declining alpha phase ($t_{1/2}=10\text{min}$), and after the age of 40 a slower beta phase, indicates uptake in organs. The absence of a relationship between anticoagulant half-life and concentration half-life may reflect factors such as protein binding of heparin.

Heparin does not have fibrinolytic activity; therefore, it will not lyse existing clots.

In the case of Solution having a concentration of 10 Units per mL heparin lock flush solution USP, it may alter, and in the case of 100 Units per mL concentrations, it will alter, the results of blood coagulation tests.

Geriatric use of heparin: Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated partial thromboplastin times (APTTs) compared with patients under 60 years of age.

CONTRAINDICATIONS:

Heparin Lock Flush Solution should not be used in patients with thrombocytopenia or with an uncontrollable active bleeding state. Heparin Lock Flush Solution, USP for IV flush should not be used for anticoagulant therapy. Heparin Lock Flush Solution is not for use in patients with documented hypersensitivity to heparin or pork products.

WARNINGS:

Heparin is not intended for intramuscular use.

Hypersensitivity - Patients with documented hypersensitivity to heparin or pork products should not receive Heparin Lock Flush Solution, USP.

Hemorrhage - Heparin should be used with extreme caution in infants and patients with disease states in which there is increased danger of hemorrhage. Some of the conditions in which increased danger of hemorrhage exists are: Cardiovascular - Subacute bacterial endocarditis, severe hypertension; Surgical - During and immediately following (a) spinal tap or spinal anesthesia or (b) major surgery, especially involving the brain, spinal cord or eye; Hematologic - conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia and some vascular purpuras; Gastrointestinal - Ulcerative lesions and continuous tube drainage of the stomach or small intestine; Neonatology - Neonatologists do not advise the use of 100 units/ml concentration in infants because of the risk of bleeding, especially in low birth weight infants; Other - Menstruation, liver disease with impaired hemostasis.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0% to 30%. Mild thrombocytopenia (count greater than $100,000/\text{mm}^3$) may remain stable or reverse even if heparin is discontinued. However, thrombocytopenia of any degree should be monitored closely. If the count falls below $100,000/\text{mm}^3$ or if recurrent thrombosis develops (See **PRECAUTIONS: White Clot Syndrome**), the heparin product should be discontinued. If continued heparin therapy is essential, administration of heparin from a different organ source can be reinstated with caution.

Coagulation Testing - Heparin Lock Flush Solution should be discontinued in the event of hemorrhage or abnormal coagulation testing results.

PRECAUTIONS:

White Clot Syndrome - It has been reported that patients on heparin may develop new thrombus formation in association with thrombocytopenia resulting from irreversible aggregation of platelets induced by heparin, the so-called "white clot syndrome". The process may lead to severe thromboembolic complications like skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke and possibly death. Therefore, heparin administration should be promptly discontinued if a patient develops new thrombosis in association with thrombocytopenia.

Drug Interactions - Avoid contact between this solution and incompatible drug products. Consult the appropriate specialized compatibility literature. Heparin Lock Flush Solutions should be used with caution in patients receiving drugs such as aspirin, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine, and others that interfere with platelet reactions (the main hemostatic defense of heparinized patients). These drugs may induce bleeding in patients receiving heparin.

Visual Inspection - Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.

Pharmacological Effects - Caution must be exercised to avoid the pharmacological effects of heparin. Consideration should be given to the cumulative amounts of heparin received from the frequent administration of Heparin Lock Flush Solution during a 24-hour period, especially in infants and the elderly. This label states also that in the case of Solution having a concentration of 10 USP Heparin Units per mL, it may alter, and that in the case of higher concentrations it will alter, the results of blood coagulation tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility - No long-term studies in animals have been performed to evaluate carcinogenic potential of heparin. Also, no reproduction studies in animals have been performed concerning mutagenesis or impairment of fertility.

Pregnancy: Teratogenic Effects Pregnancy Category C - Animal reproduction studies have not been conducted with heparin. It is also not known whether heparin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Heparin should be given to a pregnant woman only if clearly needed.

Increased risk in Older Patients, Especially Women: A higher incidence of bleeding has been reported in patients, particularly, women, over 60 years of age.

Pediatric Use: Safety and effectiveness of the 100 USP Units/mL Heparin Lock Flush Solution in pediatric patients have not been established.

Geriatric Use: A higher incidence of bleeding has been reported in patients 60 years of age, especially women (See **PRECAUTIONS**). Clinical studies indicate that lower doses of heparin may be indicated in these patients (See **CLINICAL PHARMACOLOGY** and **ADMINISTRATION**).

Nonteratogenic Effects: Heparin does not cross the placental barrier.

Nursing Mothers: Heparin is not excreted in human milk.

Laboratory Tests: Periodic platelet counts, hematocrits and tests for occult blood in stool are recommended during the entire period of use of Heparin Lock Flush Solution.

ADVERSE REACTIONS:

Hemorrhage - Hemorrhage is the chief complication that may result from heparin therapy (See **WARNINGS**). An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug. It should be appreciated that gastrointestinal or urinary tract bleeding during heparin therapy may indicate the presence of an underlying occult lesion. Bleeding can occur at any site but certain specific hemorrhage complications may be difficult to detect such as Adrenal hemorrhage, Ovarian hemorrhage and Retroperitoneal hemorrhage.

Hypersensitivity - Generalized hypersensitivity reactions have been reported with chills, fever, and urticaria as the most usual manifestations and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid

reactions, including shock occurring more rarely. Itching and burning especially on the plantar side of the feet may occur.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0-30%. While often mild and of no obvious clinical significance, such thrombocytopenia can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death (See **WARNINGS** and **PRECAUTIONS**).

Local Irritation: Local irritation and erythema have been reported with the use of Heparin Lock Flush Solution, USP.

Allergic Vasospastic Reaction: Certain episodes of painful, ischemic and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia-associated complications remains to be determined.

OVERDOSAGE:

Symptoms: Bleeding is the chief sign of heparin overdosage. Nonebleeds, blood in urine, or tarry stools may be noted as the first sign of bleeding. Easy bruising or petechial formations may precede frank bleeding.

Treatment: Neutralization of heparin effect. When clinical circumstances (bleeding) require reversal of heparinization, protamine sulfate (1% injection) by slow infusion will neutralize heparin sodium. **No more than 50mg should be administered, very slowly**, in any 10 minute period. Each mg of protamine sulfate neutralizes approximately 100 USP heparin units. The amount of protamine required decreases over time as heparin is metabolized. Although the metabolism of heparin is complex, it may, for the purpose of choosing a protamine dose, be assumed to have a half-life of about 1/2 hour after intravenous injection. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis have been reported, the drug should be given only when resuscitation techniques and treatment of anaphylactoid shock are readily available. For additional information, consult the labeling of Protamine Sulfate Injection, USP products.

ADMINISTRATION:

This product must be visually inspected for particulate matter, discoloration, cloudiness, haziness and package integrity prior to use. **FOR SINGLE USE ONLY.** Discard unused portion. **Heparin Lock Flush Solution, USP is not recommended for use in the neonate (See WARNINGS).** Geriatric Use: Patients over 60 years of age may require lower doses of heparin. The selection of the appropriate concentration of Heparin Lock Flush Solution, USP should be based on current practice standards and institutional policies and procedures. Each single volume injected into the vascular access device should be sufficient to, but not exceed, that needed to fill the device. After each use of the venous access device for injection or infusion of medication, another volume of Heparin Lock Flush solution should be injected to restore the effectiveness of the heparin lock. When the drug injection to be administered is incompatible with heparin, a flush of the intravenous access device with 0.9% Sodium Chloride Injection, USP, should precede and follow the use of the Heparin Lock Flush Solution, and appropriate literature should be consulted to verify compatibility between the drug injection and sodium chloride injection.

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

STORAGE: Store at 25° C (77°F); excursions permitted to 15° - 30°C (59°F - 86°F). Do Not Freeze.

HOW SUPPLIED:

Heparin Lock Flush Solution, USP 10 Units/mL; 5mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 10 Units/mL; 10mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 100 Units/mL; 5mL volume in 10mL syringe

INSTRUCTIONS FOR USE:

Use aseptically - Always follow CDC guidelines and your institution's procedures for IV administration.

1. Inspect package integrity including protective wrapping, syringe and tip cap. Do not use if packaging is damaged, syringe is leaking, or tip cap is displaced or missing.
2. Remove protective wrapping.
3. Visually inspect the syringe and solution. Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.
4. Remove tip cap from end of syringe.
5. Remove all air from syringe.
6. Attach the syringe to tubing or venous access device for flushing.
7. Use in accordance with any warnings or precautions appropriate to the medication being administered. Do not use if compatibility is in doubt.
8. Administer through the appropriate site a quantity of solution for maintaining the patency of the indwelling venous access device, in accordance with an appropriate protocol or the recommendation of the manufacturer of the venous access device.
9. For Single Use Only - Discard syringe and any unused portion of the solution.

Syrex, Neptune, NJ 07753

(b) (4) 10 Unit 5mL Heparin SFF

(b) (4)

Box Label

1. External lot number used, ending in AA
2. Expiration: (b) (4)
3. Order # 50092
4. Qty. 30 Pouches (two 5 mL syringes/pouch)
5. Sterile Field Heparin Lock Flush Solution, 10 Units/mL
6. Contents of undamaged, unopened packaged may be dropped in Sterile Field
7. Label is blue

Pouch Label

8. External lot number used, ending in AA
9. Expiration: (b) (4)
10. Order # 50092
11. "Push on plunger with tipcap attached to break seal" at bottom

Master Label

12. External lot number is used, ending in AA
13. Expiration: (b) (4)
14. Unit/mL Heparin Sterile Field Flush
15. 8 Boxes of 30 pkg, two 5 mL syringes/pkg
16. Store at 20°-25° C (68°-77° F)
17. Label is blue

Inner box type: Brown 10 mL Inner

Master box type: Master 10 mL

Qty. 30 Pouches (two 5 mL syringes/ pouch)

Sterile Field Heparin Lock Flush Solution, 10 Units/mL

Contents of undamaged, unopened package may be dropped in Sterile Field

For IV Flush Only For Single Use Only

- Store at 20°-25°C (68°-77°F); excursions permitted to 15°- 30°C (59°-86°F). Protect from freezing.
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- **Push on plunger with tipcap attached to break Seal.**
- See package insert for additional information.

Recommendation:

A slower administration rate is recommended to minimize a possible unpleasant taste some patients may experience.

Made in USA
Syrex, LLC
Neptune, NJ
(800) 487-4276
Order # 50092

Latex Free
Preservative Free
Terminally Sterilized
Exp. 02-01-07 Lot# 41-011-AA
(b) (4)

Lot 41-011-AA
EXP 02-01-07
Order # 50092

Push on plunger with tipcap
attached to break seal.

LOT # 41-011-AA Exp. Date: 02-01-07
10 Unit/mL Heparin Sterile Field Flush
8 Boxes of 30 pkg, two 5mL syringes/pkg
Store at 20°-25°C (68°-77°F)
ORDER #50092 41-011-AA

21

111

Heparin Lock Flush Solution, USP 10 Units/mL
Heparin Lock Flush Solution, USP 100 Units/mL

For IV Flush Only For Single Use Only

INDICATIONS FOR USE:

To maintain patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely flush the vascular access device with Heparin Lock Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy.

PRODUCT DESCRIPTION:

Each unopened and undamaged polypropylene latex-free luerlock syringe contains the labeled volume of a sterile, pyrogen-free solution of Heparin Lock Flush Solution, USP derived from porcine intestinal mucosa in 0.9% sodium chloride USP with a pH range of 5.0 - 7.5.

Heparin is a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1) α -L-iduronic acid 2-sulfate, (2)2-deoxy-2-sulfamino- α -D-glucose 6-sulfate, (3) β -D-glucuronic acid, (4)2-acetamido-2-deoxy- α -D-glucose, and (5) α -L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2)>(1)>(4)>(3)>(5), and are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is strongly acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions.

CLINICAL PHARMACOLOGY:

Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*. Heparin acts at multiple sites in the normal coagulation system. Small amount of heparin, in combination with anti-thrombin III (heparin cofactor), can inhibit thrombosis by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin. Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inactivating thrombin and preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor.

Bleeding time is usually unaffected by heparin. Clotting time is prolonged by full therapeutic doses of heparin; In most cases, it is not measurably affected by low doses of heparin. Peak plasma levels of heparin are achieved 2 to 4 hours following subcutaneous administration, although there are considerable individual variations. Loglinear plots of heparin plasma concentration with time, for a wide range of dose levels, are linear which suggests the absence of zero order processes. Liver and the reticulo-endothelial system are the sites of biotransformation. The biphasic elimination curve, a rapidly declining alpha phase ($t_{1/2}=10\text{min}$), and after the age of 40 a slower beta phase, indicates uptake in organs. The absence of a relationship between anticoagulant half-life and concentration half-life may reflect factors such as protein binding of heparin.

Heparin does not have fibrinolytic activity; therefore, it will not lyse existing clots.

In the case of Solution having a concentration of 10 Units per mL heparin lock flush solution USP, it may alter, and in the case of 100 Units per mL concentrations, it will alter, the results of blood coagulation tests.

Geriatric use of heparin: Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated partial thromboplastin times (APTTs) compared with patients under 60 years of age.

CONTRAINDICATIONS:

Heparin Lock Flush Solution should not be used in patients with thrombocytopenia or with an uncontrollable active bleeding state. Heparin Lock Flush Solution, USP for IV flush should not be used for anticoagulant therapy. Heparin Lock Flush Solution is not for use in patients with documented hypersensitivity to heparin or pork products.

WARNINGS:

Heparin is not intended for intramuscular use.

Hypersensitivity - Patients with documented hypersensitivity to heparin or pork products should not receive Heparin Lock Flush Solution, USP.

Hemorrhage - Heparin should be used with extreme caution in infants and patients with disease states in which there is increased danger of hemorrhage. Some of the conditions in which increased danger of hemorrhage exists are: Cardiovascular - Subacute bacterial endocarditis, severe hypertension; Surgical - During and immediately following (a) spinal tap or spinal anesthesia or (b) major surgery, especially involving the brain, spinal cord or eye; Hematologic - conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia and some vascular purpuras; Gastrointestinal - Ulcerative lesions and continuous tube drainage of the stomach or small intestine; Neonatology - Neonatologists do not advise the use of 100 units/mL concentration in infants because of the risk of bleeding, especially in low birth weight infants; Other - Menstruation, liver disease with impaired hemostasis.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0% to 30%. Mild thrombocytopenia (count greater than $100,000/\text{mm}^3$) may remain stable or reverse even if heparin is discontinued. However, thrombocytopenia of any degree should be monitored closely. If the count falls below $100,000/\text{mm}^3$ or if recurrent thrombosis develops (See **PRECAUTIONS: White Clot Syndrome**), the heparin product should be discontinued. If continued heparin therapy is essential, administration of heparin from a different organ source can be reinstated with caution.

Coagulation Testing - Heparin Lock Flush Solution should be discontinued in the event of hemorrhage or abnormal coagulation testing results.

PRECAUTIONS:

White Clot Syndrome - It has been reported that patients on heparin may develop new thrombus formation in association with thrombocytopenia resulting from irreversible aggregation of platelets induced by heparin, the so-called "white clot syndrome". The process may lead to severe thromboembolic complications like skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke and possibly death. Therefore, heparin administration should be promptly discontinued if a patient develops new thrombosis in association with thrombocytopenia.

Drug Interactions - Avoid contact between this solution and incompatible drug products. Consult the appropriate specialized compatibility literature. Heparin Lock Flush Solutions should be used with caution in patients receiving drugs such as aspirin, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine, and others that interfere with platelet reactions (the main hemostatic defense of heparinized patients). These drugs may induce bleeding in patients receiving heparin.

Visual Inspection - Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.

Pharmacological Effects - Caution must be exercised to avoid the pharmacological effects of heparin. Consideration should be given to the cumulative amounts of heparin received from the frequent administration of Heparin Lock Flush Solution during a 24-hour period, especially in infants and the elderly. This label states also that in the case of Solution having a concentration of 10 USP Heparin Units per mL, it may alter, and that in the case of higher concentrations it will alter, the results of blood coagulation tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility - No long-term studies in animals have been performed to evaluate carcinogenic potential of heparin. Also, no reproduction studies in animals have been performed concerning mutagenesis or impairment of fertility.

Pregnancy: Teratogenic Effects Pregnancy Category C - Animal reproduction studies have not been conducted with heparin. It is also not known whether heparin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Heparin should be given to a pregnant woman only if clearly needed.

Increased risk in Older Patients, Especially Women: A higher incidence of bleeding has been reported in patients, particularly, women, over 60 years of age.

Pediatric Use: Safety and effectiveness of the 100 USP Units/mL Heparin Lock Flush Solution in pediatric patients have not been established.

Geriatric Use: A higher incidence of bleeding has been reported in patients 60 years of age, especially women (See **PRECAUTIONS**). Clinical studies indicate that lower doses of heparin may be indicated in these patients (See **CLINICAL PHARMACOLOGY** and **ADMINISTRATION**).

Nonteratogenic Effects: Heparin does not cross the placental barrier.

Nursing Mothers: Heparin is not excreted in human milk.

Laboratory Tests: Periodic platelet counts, hematocrits and tests for occult blood in stool are recommended during the entire period of use of Heparin Lock Flush Solution.

ADVERSE REACTIONS:

Hemorrhage - Hemorrhage is the chief complication that may result from heparin therapy (See **WARNINGS**). An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug. It should be appreciated that gastrointestinal or urinary tract bleeding during heparin therapy may indicate the presence of an underlying occult lesion. Bleeding can occur at any site but certain specific hemorrhage complications may be difficult to detect such as Adrenal hemorrhage, Ovarian hemorrhage and Retroperitoneal hemorrhage.

Hypersensitivity - Generalized hypersensitivity reactions have been reported with chills, fever, and urticaria as the most usual manifestations and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid

reactions, including shock occurring more rarely. Itching and burning especially on the plantar side of the feet may occur.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0-30%. While often mild and of no obvious clinical significance, such thrombocytopenia can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death (See **WARNINGS** and **PRECAUTIONS**).

Local Irritation: Local irritation and erythema have been reported with the use of Heparin Lock Flush Solution, USP.

Allergic Vasospastic Reaction: Certain episodes of painful, ischemic and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia-associated complications remains to be determined.

OVERDOSAGE:

Symptoms: Bleeding is the chief sign of heparin overdosage. Nonebleeds, blood in urine, or tarry stools may be noted as the first sign of bleeding. Easy bruising or petechial formations may precede frank bleeding.

Treatment: Neutralization of heparin effect. When clinical circumstances (bleeding) require reversal of heparinization, protamine sulfate (1% injection) by slow infusion will neutralize heparin sodium. **No more than 50mg should be administered, very slowly**, in any 10 minute period. Each mg of protamine sulfate neutralizes approximately 100 USP heparin units. The amount of protamine required decreases over time as heparin is metabolized. Although the metabolism of heparin is complex, it may, for the purpose of choosing a protamine dose, be assumed to have a half-life of about 1/2 hour after intravenous injection. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis have been reported, the drug should be given only when resuscitation techniques and treatment of anaphylactoid shock are readily available. For additional information, consult the labeling of Protamine Sulfate Injection, USP products.

ADMINISTRATION:

This product must be visually inspected for particulate matter, discoloration, cloudiness, haziness and package integrity prior to use. **FOR SINGLE USE ONLY.** Discard unused portion. **Heparin Lock Flush Solution, USP is not recommended for use in the neonate (See WARNINGS).** Geriatric Use: Patients over 60 years of age may require lower doses of heparin. The selection of the appropriate concentration of Heparin Lock Flush Solution, USP should be based on current practice standards and institutional policies and procedures. Each single volume injected into the vascular access device should be sufficient to, but not exceed, that needed to fill the device. After each use of the venous access device for injection or infusion of medication, another volume of Heparin Lock Flush solution should be injected to restore the effectiveness of the heparin lock. When the drug injection to be administered is incompatible with heparin, a flush of the intravenous access device with 0.9% Sodium Chloride Injection, USP, should precede and follow the use of the Heparin Lock Flush Solution, and appropriate literature should be consulted to verify compatibility between the drug injection and sodium chloride injection.

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

STORAGE: Store at 25° C (77°F); excursions permitted to 15° - 30°C (59°F - 86°F). Do Not Freeze.

HOW SUPPLIED:

Heparin Lock Flush Solution, USP 10 Units/mL; 5mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 10 Units/mL; 10mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 100 Units/mL; 5mL volume in 10mL syringe

INSTRUCTIONS FOR USE:

Use aseptically - Always follow CDC guidelines and your institution's procedures for IV administration.

1. Inspect package integrity including protective wrapping, syringe and tip cap. Do not use if packaging is damaged, syringe is leaking, or tip cap is displaced or missing.
2. Remove protective wrapping.
3. Visually inspect the syringe and solution. Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.
4. Remove tip cap from end of syringe.
5. Remove all air from syringe.
6. Attach the syringe to tubing or venous access device for flushing.
7. Use in accordance with any warnings or precautions appropriate to the medication being administered. Do not use if compatibility is in doubt.
8. Administer through the appropriate site a quantity of solution for maintaining the patency of the indwelling venous access device, in accordance with an appropriate protocol or the recommendation of the manufacturer of the venous access device.
9. For Single Use Only - Discard syringe and any unused portion of the solution.

Syrex, Neptune, NJ 07753

Hospira 10 Unit Heparin 5mL SFF

NDC # 01203 63807 50020

Box Label

1. External lot number used, ending in 9D
2. Expiration: (b) (4)
3. List number E0500-20
4. Qty. 30 Pouches (two 5 mL syringes/pouch)
5. Sterile Field Heparin Lock Flush Solution, 10 Units/mL
6. Contents of undamaged, unopened packaged may be dropped in Sterile Field
7. Barcode present on label
8. Label is blue

Pouch Label

9. List: E0500-20
10. External lot number used, ending in 9D
11. Expiration: (b) (4)
12. Bar code on right hand side
13. "Push on plunger with tipcap attached to break seal" at bottom

Master Label

14. "10 Units/mL Heparin Lock Flush Solution" at top
15. External lot number used, ending in 9D
16. Expiration: (b) (4)
17. 8 Boxes of 30 pkg, two 5 mL syringes/pkg
18. Store at 20°-25° C (68°-77° F)
19. Label is blue

Inner box type: Brown 10 mL Inner

Qty. 30 Pouches (two 5 mL syringes/ pouch)

Sterile Field Heparin Lock Flush Solution, 10 Units/mL

Contents of undamaged, unopened package may be dropped in Sterile Field

For IV Flush Only For Single Use Only

- Store at 20°-25°C (68°-77°F); excursions permitted to 15°- 30°C (59°-86°F). Protect from freezing.
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
- **Push on plunger with tipcap attached to break Seal.**
- See package insert for additional information.

Recommendation:

A slower administration rate is recommended to minimize a possible unpleasant taste some patients may experience

Made in USA

Latex Free

Syrex, LLC

Preservative Free

Neptune, NJ

Terminally Sterilized

(800) 487-4276

Exp. 1 APR 2007 Lot# 19-019-9D

List # E0500-20

(b) (4)



0110363807500200

Master box type: Master 10 mL

List: E0500-20

Lot: 19-019-9D

Exp: 1 APR 2007



**Push on plunger with tipcap
attached to break seal.**

10 Units/mL Heparin Lock Flush Solution
LOT # 19-019-9D Exp. 1 APR 2007
8 BOXES OF 30 pkg, two 5 mL syringes/pkg
Store at 20°-25°C (68°-77°F)

LIST #E0500-20



0120363807500200

22
100

Heparin Lock Flush Solution, USP 10 Units/mL
Heparin Lock Flush Solution, USP 100 Units/mL

For IV Flush Only For Single Use Only

INDICATIONS FOR USE:

To maintain patency of vascular access devices designed for intermittent or infusion therapy. Prior to and after administration of intermittent medication, entirely flush the vascular access device with Heparin Lock Solution, USP. Use in accordance with any warnings or precautions appropriate to medication being administered. This device is not to be used for anticoagulant therapy.

PRODUCT DESCRIPTION:

Each unopened and undamaged polypropylene latex-free luerlock syringe contains the labeled volume of a sterile, pyrogen-free solution of Heparin Lock Flush Solution, USP derived from porcine intestinal mucosa in 0.9% sodium chloride USP with a pH range of 5.0 - 7.5.

Heparin is a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1) α -L-iduronic acid 2-sulfate, (2)2-deoxy-2-sulfamino- α -D-glucose 6-sulfate, (3) β -D-glucuronic acid, (4)2-acetamido-2-deoxy- α -D-glucose, and (5) α -L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2)>(1)>(4)>(3)>(5), and are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is strongly acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions.

CLINICAL PHARMACOLOGY:

Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*. Heparin acts at multiple sites in the normal coagulation system. Small amount of heparin, in combination with anti-thrombin III (heparin cofactor), can inhibit thrombosis by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin. Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inactivating thrombin and preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor.

Bleeding time is usually unaffected by heparin. Clotting time is prolonged by full therapeutic doses of heparin; In most cases, it is not measurably affected by low doses of heparin. Peak plasma levels of heparin are achieved 2 to 4 hours following subcutaneous administration, although there are considerable individual variations. Loglinear plots of heparin plasma concentration with time, for a wide range of dose levels, are linear which suggests the absence of zero order processes. Liver and the reticulo-endothelial system are the sites of biotransformation. The biphasic elimination curve, a rapidly declining alpha phase ($t_{1/2}=10\text{min}$), and after the age of 40 a slower beta phase, indicates uptake in organs. The absence of a relationship between anticoagulant half-life and concentration half-life may reflect factors such as protein binding of heparin.

Heparin does not have fibrinolytic activity; therefore, it will not lyse existing clots.

In the case of Solution having a concentration of 10 Units per mL heparin lock flush solution USP, it may alter, and in the case of 100 Units per mL concentrations, it will alter, the results of blood coagulation tests.

Geriatric use of heparin: Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated partial thromboplastin times (APTTs) compared with patients under 60 years of age.

CONTRAINDICATIONS:

Heparin Lock Flush Solution should not be used in patients with thrombocytopenia or with an uncontrollable active bleeding state. Heparin Lock Flush Solution, USP for IV flush should not be used for anticoagulant therapy. Heparin Lock Flush Solution is not for use in patients with documented hypersensitivity to heparin or pork products.

WARNINGS:

Heparin is not intended for intramuscular use.

Hypersensitivity - Patients with documented hypersensitivity to heparin or pork products should not receive Heparin Lock Flush Solution, USP.

Hemorrhage - Heparin should be used with extreme caution in infants and patients with disease states in which there is increased danger of hemorrhage. Some of the conditions in which increased danger of hemorrhage exists are: Cardiovascular - Subacute bacterial endocarditis, severe hypertension; Surgical - During and immediately following (a) spinal tap or spinal anesthesia or (b) major surgery, especially involving the brain, spinal cord or eye; Hematologic - conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia and some vascular purpuras; Gastrointestinal - Ulcerative lesions and continuous tube drainage of the stomach or small intestine; Neonatology - Neonatologists do not advise the use of 100 units/mL concentration in infants because of the risk of bleeding, especially in low birth weight infants; Other - Menstruation, liver disease with impaired hemostasis.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0% to 30%. Mild thrombocytopenia (count greater than 100,000/mm³) may remain stable or reverse even if heparin is discontinued. However, thrombocytopenia of any degree should be monitored closely. If the count falls below 100,000/mm³ or if recurrent thrombocytopenia develops (See **PRECAUTIONS: White Clot Syndrome**), the heparin product should be discontinued. If continued heparin therapy is essential, administration of heparin from a different organ source can be reinstated with caution.

Coagulation Testing – Heparin Lock Flush Solution should be discontinued in the event of hemorrhage or abnormal coagulation testing results.

PRECAUTIONS:

White Clot Syndrome – It has been reported that patients on heparin may develop new thrombus formation in association with thrombocytopenia resulting from irreversible aggregation of platelets induced by heparin, the so-called “white clot syndrome”. The process may lead to severe thromboembolic complications like skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke and possibly death. Therefore, heparin administration should be promptly discontinued if a patient develops new thrombosis in association with thrombocytopenia.

Drug Interactions - Avoid contact between this solution and incompatible drug products. Consult the appropriate specialized compatibility literature. Heparin Lock Flush Solutions should be used with caution in patients receiving drugs such as aspirin, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine, and others that interfere with platelet reactions (the main hemostatic defense of heparinized patients). These drugs may induce bleeding in patients receiving heparin.

Visual Inspection - Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.

Pharmacological Effects - Caution must be exercised to avoid the pharmacological effects of heparin. Consideration should be given to the cumulative amounts of heparin received from the frequent administration of Heparin Lock Flush Solution during a 24-hour period, especially in infants and the elderly. This label states also that in the case of Solution having a concentration of 10 USP Heparin Units per mL, it may alter, and that in the case of higher concentrations it will alter, the results of blood coagulation tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility – No long-term studies in animals have been performed to evaluate carcinogenic potential of heparin. Also, no reproduction studies in animals have been performed concerning mutagenesis or impairment of fertility.

Pregnancy: Teratogenic Effects Pregnancy Category C - Animal reproduction studies have not been conducted with heparin. It is also not known whether heparin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Heparin should be given to a pregnant woman only if clearly needed.

Increased risk in Older Patients, Especially Women: A higher incidence of bleeding has been reported in patients, particularly, women, over 60 years of age.

Pediatric Use: Safety and effectiveness of the 100 USP Units/mL Heparin Lock Flush Solution in pediatric patients have not been established.

Geriatric Use: A higher incidence of bleeding has been reported in patients 60 years of age, especially women (See **PRECAUTIONS**). Clinical studies indicate that lower doses of heparin may be indicated in these patients (See **CLINICAL PHARMACOLOGY** and **ADMINISTRATION**).

Nonteratogenic Effects: Heparin does not cross the placental barrier.

Nursing Mothers: Heparin is not excreted in human milk.

Laboratory Tests: Periodic platelet counts, hematocrits and tests for occult blood in stool are recommended during the entire period of use of Heparin Lock Flush Solution.

ADVERSE REACTIONS:

Hemorrhage - Hemorrhage is the chief complication that may result from heparin therapy (See **WARNINGS**). An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug. It should be appreciated that gastrointestinal or urinary tract bleeding during heparin therapy may indicate the presence of an underlying occult lesion. Bleeding can occur at any site but certain specific hemorrhage complications may be difficult to detect such as Adrenal hemorrhage, Ovarian hemorrhage and Retroperitoneal hemorrhage.

Hypersensitivity - Generalized hypersensitivity reactions have been reported with chills, fever, and urticaria as the most usual manifestations and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid

reactions, including shock occurring more rarely. Itching and burning especially on the plantar side of the feet may occur.

Thrombocytopenia - Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0-30%. While often mild and of no obvious clinical significance, such thrombocytopenia can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death (See **WARNINGS** and **PRECAUTIONS**).

Local Irritation: Local irritation and erythema have been reported with the use of Heparin Lock Flush Solution, USP.

Allergic Vasospastic Reaction: Certain episodes of painful, ischemic and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia-associated complications remains to be determined.

OVERDOSAGE:

Symptoms: Bleeding is the chief sign of heparin overdosage. Nonebleeds, blood in urine, or tarry stools may be noted as the first sign of bleeding. Easy bruising or petechial formations may precede frank bleeding.

Treatment: Neutralization of heparin effect. When clinical circumstances (bleeding) require reversal of heparinization, protamine sulfate (1% injection) by slow infusion will neutralize heparin sodium. **No more than 50mg should be administered, very slowly**, in any 10 minute period. Each mg of protamine sulfate neutralizes approximately 100 USP heparin units. The amount of protamine required decreases over time as heparin is metabolized. Although the metabolism of heparin is complex, it may, for the purpose of choosing a protamine dose, be assumed to have a half-life of about 1/2 hour after intravenous injection. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis have been reported, the drug should be given only when resuscitation techniques and treatment of anaphylactoid shock are readily available. For additional information, consult the labeling of Protamine Sulfate Injection, USP products.

ADMINISTRATION:

This product must be visually inspected for particulate matter, discoloration, cloudiness, haziness and package integrity prior to use. FOR SINGLE USE ONLY. Discard unused portion. **Heparin Lock Flush Solution, USP is not recommended for use in the neonate (See WARNINGS).** Geriatric Use: Patients over 60 years of age may require lower doses of heparin. The selection of the appropriate concentration of Heparin Lock Flush Solution, USP should be based on current practice standards and institutional policies and procedures. Each single volume injected into the vascular access device should be sufficient to, but not exceed, that needed to fill the device. After each use of the venous access device for injection or infusion of medication, another volume of Heparin Lock Flush solution should be injected to restore the effectiveness of the heparin lock. When the drug injection to be administered is incompatible with heparin, a flush of the intravenous access device with 0.9% Sodium Chloride Injection, USP, should precede and follow the use of the Heparin Lock Flush Solution, and appropriate literature should be consulted to verify compatibility between the drug injection and sodium chloride injection.

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

STORAGE: Store at 25° C (77°F); excursions permitted to 15° - 30°C (59°F - 86°F). Do Not Freeze.

HOW SUPPLIED:

Heparin Lock Flush Solution, USP 10 Units/mL; 5mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 10 Units/mL; 10mL volume in 10mL syringe
Heparin Lock Flush Solution, USP 100 Units/mL; 5mL volume in 10mL syringe

INSTRUCTIONS FOR USE:

Use aseptically - Always follow CDC guidelines and your institution's procedures for IV administration.

1. Inspect package integrity including protective wrapping, syringe and tip cap. Do not use if packaging is damaged, syringe is leaking, or tip cap is displaced or missing.
2. Remove protective wrapping.
3. Visually inspect the syringe and solution. Do not use if solution contains a precipitate or is discolored, cloudy or hazy. Do not use if the container is damaged, leaking, or opened.
4. Remove tip cap from end of syringe.
5. Remove all air from syringe.
6. Attach the syringe to tubing or venous access device for flushing.
7. Use in accordance with any warnings or precautions appropriate to the medication being administered. Do not use if compatibility is in doubt.
8. Administer through the appropriate site a quantity of solution for maintaining the patency of the indwelling venous access device, in accordance with an appropriate protocol or the recommendation of the manufacturer of the venous access device.
9. For Single Use Only - Discard syringe and any unused portion of the solution.

Syrex, Neptune, NJ 07753

(b) (4) / Syrex 10mL

Film barcode # 10010

Box Label

Master Label

1. External lot number used, ending in BB
2. Expiration: (b) (4)
3. Item number ends in 76
4. (b) (4)
5. Each label has numbers 1.- 10. on left side
6. Qty 100 is not too close to top edge
7. S-10 is written under Qty. 100
8. Top of label says Syrex 10 mL – 0.9% Sodium Chloride Injection USP

9. External lot number top left and bottom right
10. Expiration: (b) (4)
11. Item number ends in 76
12. 12 BOXES OF 100 SYRINGES
13. QTY. 1,200 SYRINGES
14. Text is not cut off on left or right edge
15. Label is white
16. Top of label says 10.0 ML SALINE FLUSH SYRINGE

Inner box type: 10 mL Inner
(1 bundle packages 75,000 syringes)

Master box type: 10/12 Master
(1 bundle packages 210,000 syringes)

23

18

Qty 100
S-10

Syrex 10mL – 0.9% Sodium Chloride Injection USP

Sterile fluid and fluid pathway. Each Syrex syringe, unopened and undamaged, contains 10mL (-0/+1mL) of a sterile, pyrogen-free isotonic solution of 0.9% Sodium Chloride Injection USP, with an osmolarity of 0.31mOsm/L, pH 4.5 – 7.0. **Pharmacology:** 0.9% Sodium Chloride Injection USP is a sterile aqueous injection having approximately the same osmotic pressure and composition as extracellular fluids. It is non-irritating to tissues. **Indications and Usage:** For use as a sterile isotonic vehicle for IV flush only. **Contraindications:** Hypermnatremia and fluid retention, when the administration of sodium or chloride could be clinically detrimental. **Precautions:** If compatibility is in doubt, consult the appropriate specialized literature. **Do not use if solution is discolored or contains a precipitate.** **Administration:** This product should be inspected visually for particulate matter and discoloration prior to use. **Caution:** Federal (USA) law prohibits dispensing this device without prescription. Store at controlled room temperature (15°C – 30°C). **Do not freeze.** Do not place in a sterile field.

Instructions for use

Use Aseptically – For IV Flush Only. Follow CDC guidelines and your institution’s procedures for IV flush administration.

1. Inspect package integrity including protective wrapping, syringe and tip cap. Do Not Use if packaging is damaged, syringe is leaking or tip cap is not fully attached to syringe.
2. Remove protective wrapping.
3. Visually inspect the syringe and solution. Do not use if cloudy or hazy. Do not use if the syringe/tip cap is damaged, syringe is leaking or tip cap is not fully attached to syringe.
4. **Push on plunger with tipcap attached to break seal.**
5. Remove tip cap from end of syringe.
6. Attach blunt cannula or needle if required.
7. Hold syringe with tip upward, tap side for bubbles to rise, apply and maintain pressure to plunger until all air is expelled from the syringe (and needle or blunt cannula if attached).
8. Use in accordance with any warnings or precautions appropriate to the medication being administered. Do not use if compatibility is in doubt.
9. Administer through the appropriate site a quantity of solution for maintaining the patency of the indwelling venous access device.
10. For Single Use Only – Discard syringe and any unused portion of the solution.

Recommendation: A slower administration rate is recommended to minimize a possible unpleasant taste patients may experience

Latex Free
Preservative Free
(b) (4)

LOT 21-014-BB
EXP 08-01-07
ITEM # 513576

Made in USA
(800) 487-4276
Syrex Neptune, NJ

10.0 ML SALINE FLUSH SYRINGE
LOT#21-014-BB EXP DATE: 08-01-07
12 BOXES OF 100
QTY. 1,200 SYRINGES
ITEM # 513576 21-014-BB

Attachment 3

INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): 2053120

Device Name: Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Indications For Use:

Excelsior Sterile Field Saline Flush Syringes and Heparin Lock Flush Syringes are indicated for use in flushing IV catheters and IV tubing.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment 4

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities: To the best of my knowledge, the verification activities for the modifications as identified in the **Summary of Design Control Activities** section of the Cover Letter were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Ruben Martinez, Regulatory/Quality

10-31-05

Date

Manufacturer: With regard to the Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes, the manufacturer, Excelsior Medical Corporation, 1923 Heck Avenue, Neptune, NJ 07753, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Ruben Martinez, Regulatory/Quality

10-31-05

Date

Attachment 5

510(k) SUMMARY

510(k) SUMMARY

Submitted by:

Ruben Martinez
Director, Regulatory/Quality
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 97753

Proposed Device:

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes

Predicate Device:

Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes

Device Description and Statement of Intended Use:

The modification which is the subject of this Special 510(k) is substitution of the current dust cover packaging with Sterile Field packaging. All other aspects of the product design remain unchanged.

Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes are intended for flushing IV catheters and IV tubing. This is the same intended use previously cleared for the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes.

Summary of Technological Characteristics of New Device to Predicate Device

The technological characteristics of Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes do not differ from the currently marketed Excelsior Saline Flush Syringes and Heparin Lock Flush Syringes. The devices use the same fundamental scientific technology and have the same intended use.

Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

Attachment 6

TRUTHFUL AND ACCURACY STATEMENT

CERTIFICATION OF TRUTHFULNESS AND ACCURACY

I certify that, in my capacity as Director, Regulatory/Quality for Excelsior Medical Corporation, 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 related to a substantial equivalence decision has been omitted.



Ruben Martinez
Director, Regulatory/Quality

10-31-05
Date

From: Reviewer(s) - Name(s) [Signature]
Subject: 510(k) Number K053120/S1

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. *MR 12/27/05*
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.).

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

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices *N/A MR 12/26/05*
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A MR 12/26/05

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs): *N/A MR 12/16/05*

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 day

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

FO2/Class II/880.5200
Review: [Signature] 11CB 12/7/05
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] IND 12-08-05
(Division Director) (Date)

K053120/SJ

Internal Administrative Form

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

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER S001/ K053120

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

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.)
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 (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, 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**.
This change was to replace the existing "dust cover" packaging for sterile Saline and Heparin Lock Flush Syringes with packaging that acts as a sterile barrier to allow the exterior surfaces of the syringes as well as the fluid path to be sterile as long as the packaging is not opened.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, same labeling, same intended use, same physical characteristics, same operating principle, same scientific technology; same prefilled syringes flush solutions (saline and heparin), same materials and same sterilization process. The differences rely on the packaging material. Chevron pouches are intended to replace the Polypropylene dust covers used in the predicate. Chevron pouches are made of 3.3mil white surgical Kraft paper and one part 1.75mil clear PP/PET laminate.
5. A **Design Control Activities Summary** which includes:
 - 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. The sponsor provided a list of performance testing to assess stability and the ability of the modified package to maintain sterility of the subject device.
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used.
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - 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.
(Needs to revise (i)).
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure** (and Class III Summary for Class III devices).



(Reviewer's Signature)

12/07/05
(Date)

Comments

See attached review memorandum dated December 6, 2005 for a summary review of the information provided in this premarket notification K053120/ S001.

revised:8/1/03

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K053120/ S001

Reviewer: Michelle Rios

Division/Branch: DAGID/ INCB

Device Name: **Sterile Saline and Heparin Lock Flush Syringes**

Product To Which Compared (510(K) Number If Known): _____

		YES	NO	
1.	Is Product A Device	√		If NO = Stop
2.	Is 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 NO = Go To 10 If YES = Stop SE
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?	√		Final Decision:SE December 6, 2005

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The **Sterile Saline and Heparin Lock Flush Syringes** are indicated for use in flushing IV catheters and IV tubing.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

See attached memorandum dated December 6, 2005.

S001
K053120 Sterile Saline and Heparin Lock Flush Syringes

MEMORANDUM
S001/ K053120

DATE: December 6, 2005

FROM: **Michelle Rios**, Microbiologist, CDRH, ODE, DAGID, HFZ-480

THROUGH: Sheila Murphey, MD; Chief, Infection Control Devices Branch

SUBJECT: S001/ K053120 Sterile Saline and Heparin Lock Flush Syringes
Excelsior Medical
Proposed Product Code/Class: **FOZ/ Class II/ 880.5200**
Contact: Ruben Martinez
1923 Heck Avenue
Neptune, NJ 07753
Telephone: 732-776-752 Fax: 732-776-7600 email: rmartinez@excelsiormedical.com

TO: The Record

BACKGROUND

The firm submitted a special 510(k) for their Sterile Saline and Heparin Lock Flush Syringes to replace the existing "dust cover" packaging for the subject device with packaging that acts as a sterile barrier. The packaging used for the predicate devices was polypropylene. The package used for the predicate is intended to be replaced with Chevron pouches. Chevron pouches is a two-part envelope, made with one part 3.3 mil white Surgical Kraft paper and one part 1.75 mil clear PP/ PET laminate. The Kraft paper contains printed information.

On a fax dated November 22, 2005, the Agency requested additional information from the sponsor in regards to the terminal sterilization process used for the subject device when compared to the predicate. Additional administrative requirements were also requested to complete the review of the device that is the subject of this submission.

On November 30, 2005, the sponsor submitted supplemental information (S001) in response to the additional information requested by the Agency.

INDICATION FOR USE

The **Sterile Saline and Heparin Lock Flush Syringes** are indicated for use in flushing IV catheters and IV tubing.

COMPARISON INFORMATION

The sponsor provided brief statements that addressed their predicate similarities with the devices that are the subject of this submission.

S001
K053120 Sterile Saline and Heparin Lock Flush Syringes

Description	K962938 Saline Flush Syringe	K023740 Heparin Lock Flush Syringe	K053120 Saline and Heparin Lock Flush Syringe
Intended Use	Flushing IV Catheters and IV Tubing	Flushing IV Catheters and IV Tubing	Same
Operating Principle	Flush prior to and after administration of intermittent medication	Flush prior to and after administration of intermittent medication	Same
Mechanical	Syringe	Syringe	Syringe
Flush Solution	Saline 0.9%	Heparin 10 and 100 USP units/mL in 0.9% Saline	Same for saline and heparin, respectively.
Materials	Purchased sterile	Purchased sterile	Purchased sterile
Sterilization Process*	(b) (4)	(b) (4)	(b) (4)

(b) (4)

(b) (4)

S001 Response: (b) (4)

Conclusion: (b) (4)

PERFORMANCE TESTING

The sponsor stated that additional testing was performed to verify that the modified package meets the acceptance criteria. The tests performed are listed below:

USP Sterility test for the external syringe surface
ISO 11607:1997E - Dye Penetration Test
ASTM F88-85 Tensile Strength
ASTM 1140 Burst Test
ASTM F1608 Microbial Ranking
USP <87> Abnormal Toxicity
Whole Package Integrity Test

S001
K053120 Sterile Saline and Heparin Lock Flush Syringes

The firm stated that the acceptance criteria were met for each test performed. No data was provided/ reviewed for the above tests. This is acceptable for Special 510Ks.

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS (Attachment 4, original)

Per Ruben Martinez, Director of Regulatory/ Quality certified to the best of his knowledge that the designated individuals performed all verification activities and the results demonstrated that the predetermined acceptance criteria were met. In addition, Ruben Martinez, certified that with regard to the Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes, the manufacturer, Excelsior Medical Corporation is in conformance with the design control requirements as specified by 21 CFR 820.30 and the records are available for review.

The sponsor was asked to (b) (4)

S001 Response: An acceptable Declaration of conformity with design controls was provided (Attachment 8, S001).

LABELING (Pages 16-23, original)

The labeling for the modified package for the subject device was reviewed to verify that the indication for use for the device was not affected by the modification. However, the Agency needs clarification in regards to the labeling for the subject device. The firm included in the submission the labeling used for the predicate and the labeling used for the device that is the subject of this 510K. Below is a list of reference of each label included in this premarket notification.

The sponsor stated in a telephone communication that (b) (4) are distributors and that the labeling for each are the same.

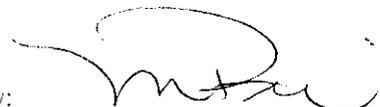
The sponsor provided the proposed labeling for the two lock flush solutions that are the subject of this submission.

	Predicate	K053120
Saline	(b) (4)	
Heparin		

CONCLUSION/ RECOMMENDATION

The information provided by EXCELSIOR MEDICAL completes the review of this submission. Based on the additional information provided EXCELSIOR MEDICAL in their response referencing their 510(k) submission for **Sterile Saline and Heparin Lock Flush Syringes (S001/ K053120)**, please consider my recommendation of substantial equivalence to other legally marketed lock flush solutions syringes.

Reviewed by:


Michelle Rios, MS

From: Reviewer(s) - Name(s) W. P. R.

Subject: 510(k) Number K053120

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

- Refused to accept.
- Requires additional information (other than refuse to accept). *file 11/22/05*
- 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 *N/A MR 11/17/05*
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A MR 11/17/05

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs): *N/A MR 11/17/05*
 No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

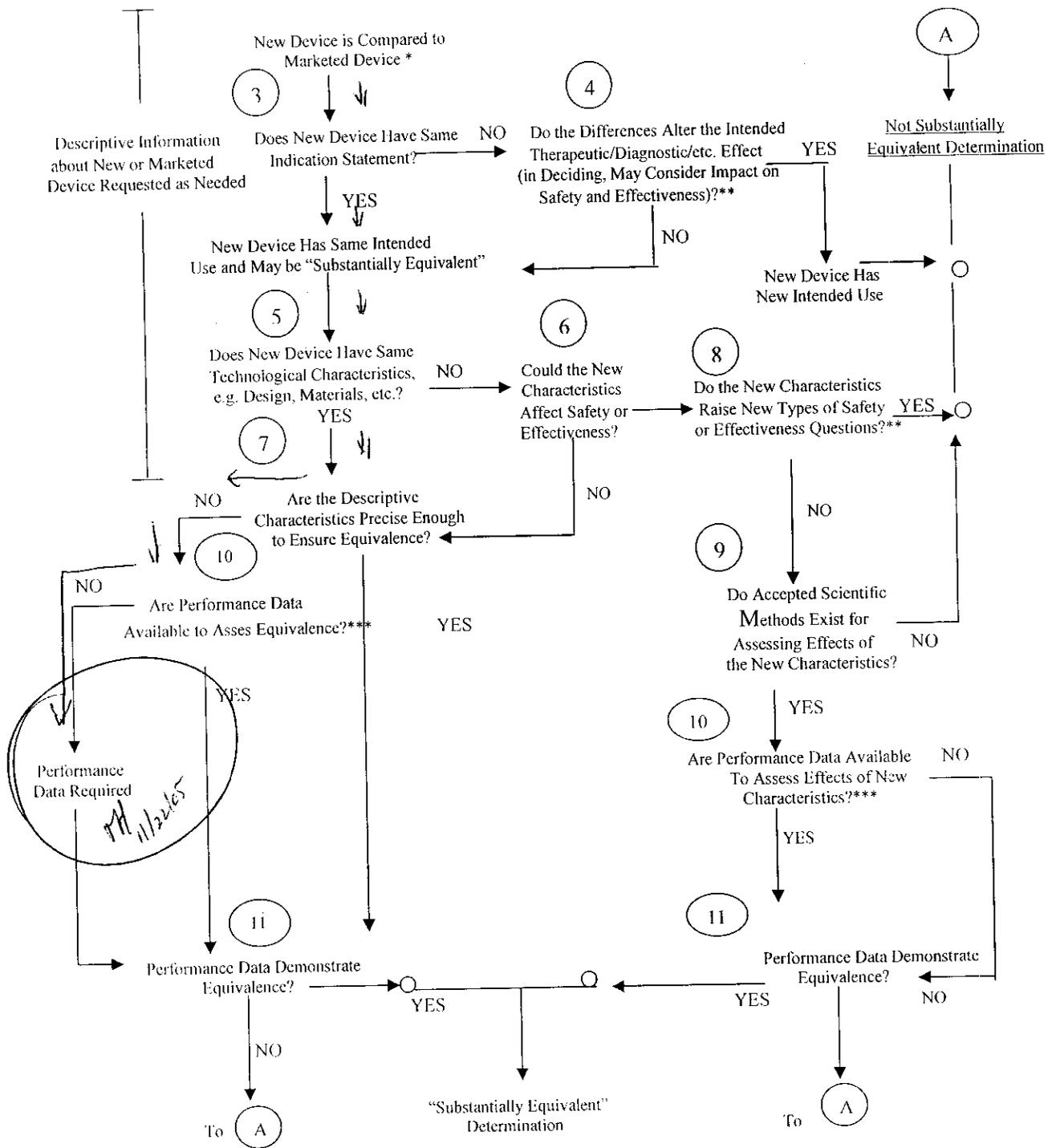
Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

8021 II / 890-5200
Review: Shirley A. Mangione / MCB (Branch Chief) (Branch Code) 11/22/05 (Date)

Final Review: _____ (Date)
(Division Director)

k053120

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.

K053120

Internal Administrative Form

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

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

510(k) Number: K053120

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
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.	✓	
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. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - 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 submitter'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 submitter's unmodified predicate device.	-	
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.		
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.]		

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>

*** TX REPORT ***

TRANSMISSION OK

TX/RX NO	0589	
CONNECTION TEL		917327767600
SUBADDRESS		
CONNECTION ID		
ST. TIME	11/22 14:41	
USAGE T	00'58	
PGS.	3	
RESULT	OK	

**DHHS/FDA/CDRH/ODE
 DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL,
 INFECTION CONTROL AND DENTAL DEVICES
 9200 CORPORATE BOULEVARD, HFZ-480
 ROCKVILLE, MARYLAND 20850**

**FROM: MICHELLE RIOS
 MICROBIOLOGIST
 INFECTION CONTROL DEVICES BRANCH
 Phone number: 301-443-8913 ext.151 Fax NO. 301-480-3002
 Email address: michelle.rios@fda.hhs.gov**

DATE: November 22, 2005

NO. OF PAGES: 3 (including cover sheet)

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR K053120

**TO: Ruben Martinez
 Excelsior Medical Corporation**

FAX: 732-776-7600

PLEASE REVIEW ATTACHED REVIEW SUMMARY FOR A LISTING OF ADDITIONAL INFORMATION REQUIRED TO COMPLETE REVIEW OF THE ABOVE SUBMISSION. YOU MAY FAX YOUR RESPONSE TO ME AND MAIL THE HARD COPY TO THE DOCUMENT MAIL CENTER. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT MICHELLE RIOS.

This submission will be placed on TELEPHONE HOLD until requested information is provided by the firm.

NOTE: PLEASE "SEND E-MAIL, RETURN FAX, OR LEAVE

**DHHS/FDA/CDRH/ODE
DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL,
INFECTION CONTROL AND DENTAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850**

FROM: MICHELLE RIOS
MICROBIOLOGIST
INFECTION CONTROL DEVICES BRANCH
Phone number: 301-443-8913 ext.151 Fax NO. 301-480-3002
Email address: michelle.rios@fda.hhs.gov

DATE: November 22, 2005

NO. OF PAGES: 3 (including cover sheet)

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR K053120

TO: Ruben Martinez
Excelsior Medical Corporation

FAX: 732-776-7600

PLEASE REVIEW ATTACHED REVIEW SUMMARY FOR A LISTING OF ADDITIONAL INFORMATION REQUIRED TO COMPLETE REVIEW OF THE ABOVE SUBMISSION. YOU MAY FAX YOUR RESPONSE TO ME AND MAIL THE HARD COPY TO THE DOCUMENT MAIL CENTER. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT MICHELLE RIOS.

This submission will be placed on TELEPHONE HOLD until requested information is provided by the firm.

NOTE: PLEASE "SEND E-MAIL, RETURN FAX, OR LEAVE VOICE MAIL MESSAGE" TO CONFIRM RECEIPT OF THE ABOVE FAX. THANKS,

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

REQUEST FOR ADDITIONAL INFORMATION

DATE: November 22, 2005

FROM: Michelle Rios, Microbiologist, CDRH, ODE, DAGID, HFZ-480

THROUGH: Sheila Murphey, MD; Chief, Infection Control Devices Branch

SUBJECT: K053120 Sterile Saline and Heparin Lock Flush Syringes
Proposed Product Code/Class: **FOZ/ Class II/ 880.5200**

TO: Contact: Ruben Martinez
Telephone: 732-776-752 Fax: 732-776-7600 email: rmartinez@excelsiormedical.com

We cannot determine if the subject device is substantially equivalent to a legally marketed predicate device based solely on the information that you have provided in your 510(k) submission for Sterile Saline and Heparin Lock Flush Syringes (K053120). To complete the review of this submission, we require that you provide the following additional information:

(b) (4) STERILIZATION PROCESS:

You stated in your submission that the sterilization process was (b) (4)

[REDACTED]

1. (b) (4)

Please be advised that (b) (4)

2. You should provide to the Agency additional data that demonstrates that the (b) (4)

3. In addition, please be advised that if the (b) (4)

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

4. Please revise the declaration of conformity to design controls statement to include the word validation in the first sentence to read: (b) (4)

LABELING (Pages 16-23)

5. Please provide the proposed labeling for the Heparin Lock Flush Syringes for FDA review.

(b) (4)

Reviewed by:



Michelle Rios

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K053120

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

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.)
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 (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**, 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**.
This change was to replace the existing "dust cover" packaging for sterile Saline and Heparin Lock Flush Syringes with packaging that acts as a sterile barrier to allow the exterior surfaces of the syringes as well as the fluid path to be sterile as long as the packaging is not opened.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, operating principle, scientific technology, same flush solutions prefilled syringes, materials and sterilization process.
5. A **Design Control Activities Summary** which includes:
 - 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. A list of performance testing to assess stability and sterility of the modified device was provided.
 - 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 (Not included)
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - 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.
(Needs to revise (i)).
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**



(Reviewer's Signature)

11/22/05
(Date)

Comments

See attached review memorandum dated November 22, 2005 for a list of recommended additional information.

revised:8/1/03

MEMORANDUM

DATE: November 22, 2005
FROM: Michelle Rios, Microbiologist, CDRH, ODE, DAGID, HFZ-480
THROUGH: Sheila Murphey, MD; Chief, Infection Control Devices Branch
SUBJECT: K053120 Sterile Saline and Heparin Lock Flush Syringes
Excelsior Medical
Proposed Product Code/Class: **FOZ/ Class II/ 880.5200**
Contact: Ruben Martinez
1923 Heck Avenue
Neptune, NJ 07753
Telephone: 732-776-752 Fax: 732-776-7600 email: rmartinez@excelsiormedical.com
TO: The Record

Sheila Murphey MD
11/22/05

ADMINISTRATIVE REQUIREMENTS

Excelsior Medical submitted a special pre-market notification for their Sterile Saline and Heparin Lock Flush Syringes. The firm submitted the following administrative items:

- A. The Truthful and Accurate Statement signed by Ruben Martinez, Director Regulatory/ Quality – As required by 21 CFR 807.87(j) – Acceptable
- B. Indication for Use Statement (page 25) – Acceptable
- C. 510(k) Summary (page 29) - Not reviewed

INDICATION FOR USE

The **Sterile Saline and Heparin Lock Flush Syringes** are indicated for use in flushing IV catheters and IV tubing.

In addition to the above statement, the sponsor included in their indication for use for the predicate the directions for use of each of the devices that are the subject of this submission. This is not necessary for the purposes of this premarket notification. The indication for use is not altered.

BACKGROUND

The firm submitted a special 510(k) for their Sterile Saline and Heparin Lock Flush Syringes to replace the existing “dust cover” packaging for the subject device with packaging that acts as a sterile barrier. The packaging used for the predicate devices was polypropylene. The package used for the predicate is intended to be replaced with Chevron pouches. Chevron pouches is a two-part envelope, made with one part 3.3 mil white Surgical Kraft paper and one part 1.75 mil clear PP/ PET laminate. The Kraft paper contains printed information.

COMPARISON INFORMATION

The sponsor provided brief statements that addressed their predicate similarities with the devices that are the subject of this submission.

K053120 Sterile Saline and Heparin Lock Flush Syringes

Description	K962938 Saline Flush Syringe	K023740 Heparin Lock Flush Syringe	K053120 Saline and Heparin Lock Flush Syringe
Intended Use	Flushing IV Catheters and IV Tubing	Flushing IV Catheters and IV Tubing	Same
Operating Principle	Flush prior to and after administration of intermittent medication	Flush prior to and after administration of intermittent medication	Same
Mechanical	Syringe	Syringe	Syringe
Flush Solution	Saline 0.9%	Heparin 10 and 100 USP units/mL in 0.9% Saline	Same for saline and heparin, respectively.
Materials	Purchased sterile	Purchased sterile	Purchased sterile
Sterilization Process*	(b) (4)	(b) (4)	(b) (4)

(b) (4)

(b) (4)

PERFORMANCE TESTING

The sponsor stated that additional testing was performed to verify that the modified package meets the acceptance criteria. The tests performed are listed below:

USP Sterility test for the external syringe surface
ISO 11607:1997E - Dye Penetration Test
ASTM F88-85 Tensile Strength
ASTM 1140 Burst Test
ASTM F1608 Microbial Ranking
USP <87> Abnormal Toxicity
Whole Package Integrity Test

The firm stated that the acceptance criteria were met.

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS (Attachment 4)

Per Ruben Martinez, Director of Regulatory/ Quality certified to the best of his knowledge that the designated individuals performed all verification activities and the results demonstrated that the predetermined acceptance criteria were met. In addition, Ruben Martinez, certified that with regard to the Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes, the manufacturer, Excelsior Medical Corporation is in conformance with the design control requirements as specified by 21 CFR 820.30 and the records are available for review.

The sponsor should revise the above statement to include validation in the first sentence to read: "... to the best of my knowledge, the verification and validation activities for the modifications..."

K053120 Sterile Saline and Heparin Lock Flush Syringes

LABELING (Pages 16-23)

5. Please provide the proposed labeling for the Heparin Lock Flush Syringes for FDA review.

(b) (4)

A large black rectangular redaction box covers the majority of the page content below the question number 5.

Reviewed by:



Michelle Rios, MS

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K053120

Reviewer:Michelle Rios

Division/Branch:DAGID/ INCB

Device Name: **Sterile Saline and Heparin Lock Flush Syringes**

Product To Which Compared (510(K) Number If Known): _____

		YES	NO	
1.	Is Product A Device	x		If NO = Stop
2.	Is Device Subject To 510(k)?	x		If NO = Stop
3.	Same Indication Statement?	x		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?	x		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		x	If NO = Go To 10 If YES = Stop SE
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?		x	If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision:TH November 22, 2005

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The **Sterile Saline and Heparin Lock Flush Syringes** are indicated for use in flushing IV catheters and IV tubing.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

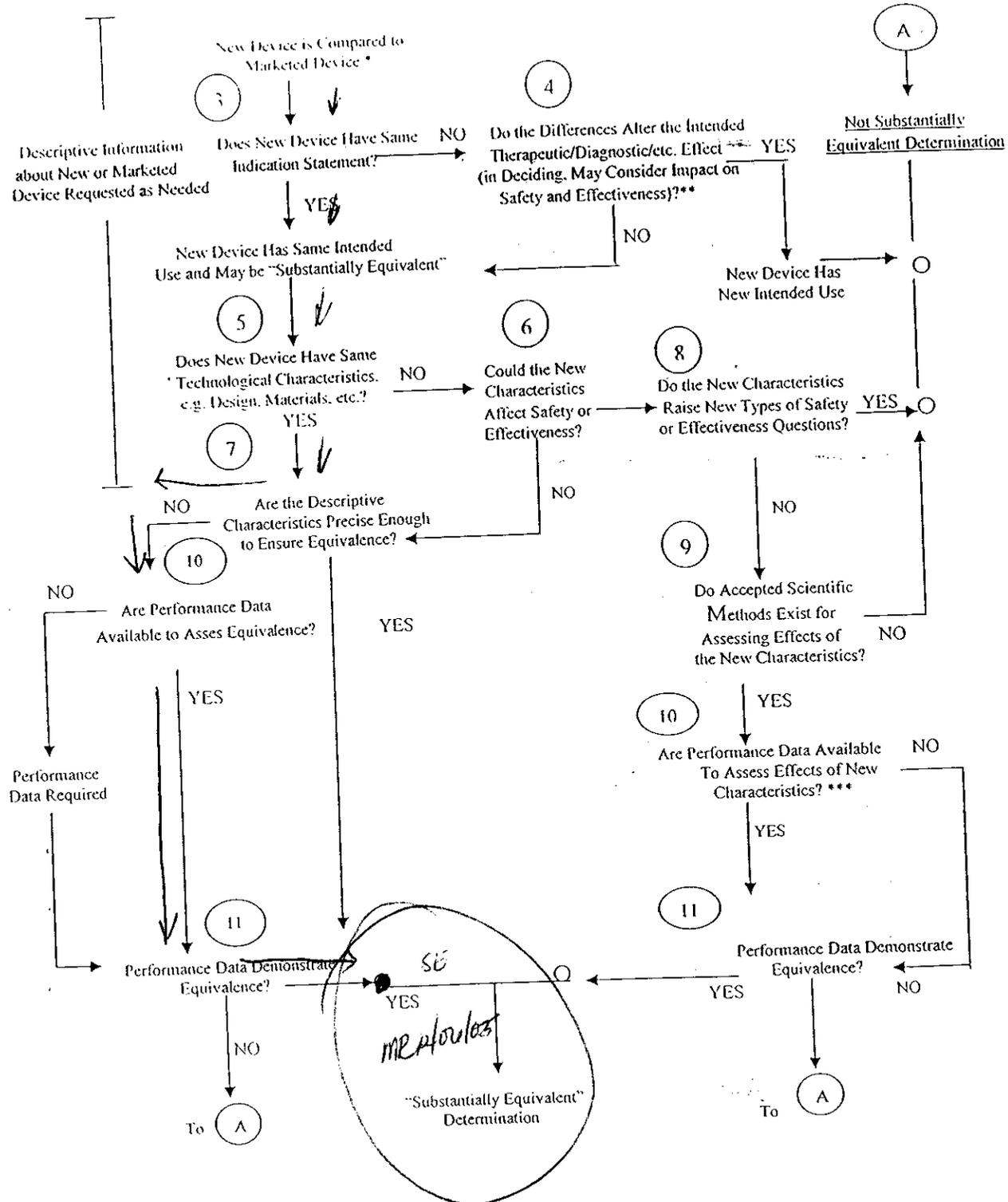
1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

See attached memorandum dated November 22, 2005.

5001 / 1053120

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.

December 01, 2005

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

EXCELSIOR MEDICAL CORP.
1923 HECK AVE.
NEPTUNE, NJ 07753
ATTN: RUBEN MARTINEZ

510(k) Number: K053120
Product: STERILE FIELD
SALINE AND
HEPARIN LOCK
FLUSH SYRINGES

The additional information you have submitted has been received.

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

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

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



K053120/S'

Date: November 28, 2005

From: Ruben Martinez

R. Martinez

Through: Sheila Murphey, MD; Chief, Infection Control Devices Branch

Subject: K053120 Sterile Saline and Heparin Lock Flush Syringes
Proposed Product Code/Class: **FOZ/Class II/880.5200**

To: Michelle Rios, Microbiologist, CDRH, ODE, DAGID, HFZ-480

RE: Request for Additional Information

Request #1

Please clarify which (b) (4) sterilization process was used for each device that are the subject of this submission.

Response:

With this letter, Excelsior Medical is confirming that (b) (4)

It is important to follow a chronology of events leading to the current process used at Excelsior at the present time. For easy of review the information is provided below.

Background- Saline Flush syringe

- (b) (4)

1923 Heck Avenue * Neptune NJ * 07753 * 732-776-7525 * 732-776-7600

K28

- (b) (4) [Redacted]
- (b) (4) [Redacted]

Background- Heparin Lock Flush Syringe

- (b) (4) [Redacted]

Conclusions:

- (b) (4) [Redacted]

Request #4

Declaration of conformity to design controls statement needs to be revised to include the word validation.

Response:

- Declaration revised to include the word validation. 2 originals signed and included as attachment # 8

Request # 5

Provide the proposed labeling for Heparin Lock Flushes for FDA review.

Response:

- (b) (4) 10 Unit Heparin SFF (5ml) provided- refer to page # 21 of original submission
- (b) (4) 10 Unit Heparin SFF (5ml) provided- refer to page #22 of original submission

ATTACHMENT 1

July 23, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Pre-market Notification Registration Number 2027791

Attention Document Control Clerk:

Please note that Excelsior Medical Corporation intends to manufacture and market a disposable syringe that is prefilled with normal saline (.9% sodium chloride)

A similar device is currently being marketed by (b) (4). Their device is marketed under the name (b) (4). It is our understanding that Vital Signs obtained 510(k) clearance within the last year.

The following is a summary of the Excelsior device.

1. Excelsior intends to use (b) (4) (b) (4) disposable syringes for its device. Ideally, the (b) (4) shall be primarily used, however, the (b) (4) shall be also available to satisfy market demand. Excelsior intends to use (b) (4) to seal the tip of the syringe and prevent touch contamination and leakage.
2. Excelsior intends to use sterile normal saline solution manufactured by (b) (4) (b) (4). Other FDA approved manufacturer's product may be substituted.
3. Excelsior shall label the syringe with the following information: volume, contents - normal saline, expiration date and lot number.
4. Syringes shall be filled (b) (4) (b) (4). Packaging shall be 30 per box and several boxes per shipping case.
5. Excelsior's device shall be quite similar to the (b) (4) to what is currently being used in hospitals and home healthcare facilities across the country.

6. Sterility assurance shall be maintained with an SAL of (b) (4) (b) (4)
7. Excelsior's devices may be packaged individually in plastic pouches and heat sealed for tamper evidence purposes.
8. Excelsior's labelling will be exactly identical to that of the Vyringe device. Excelsior's labeling will be as follows:

Excelsior Medical Corporation (800)4U-Pharm

Normal Saline 10ml Lot No. 123456 Expiration date: 12/25/96

Contents sterile, non-pyrogenic in undamaged package.

Use aseptically. For single use only.

Destroy after use or after expiration date.

Instructions for use:

Read product label to verify contents and expiration date.

Check plastic bag for damage.

Tear open plastic bag and remove syringe.

Pull/twist off the tip cap at end of syringe.

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

9. Safety and effectiveness information will be made available to interested persons upon request.
10. The Excelsior device is identical to other devices of similar use both in material and specifications.
11. I have enclosed a sample of the Excelsior device.

If I can be of any assistance, please call me during normal working hours. Please process this pre-market notification as quickly as possible. Thank you for your help.

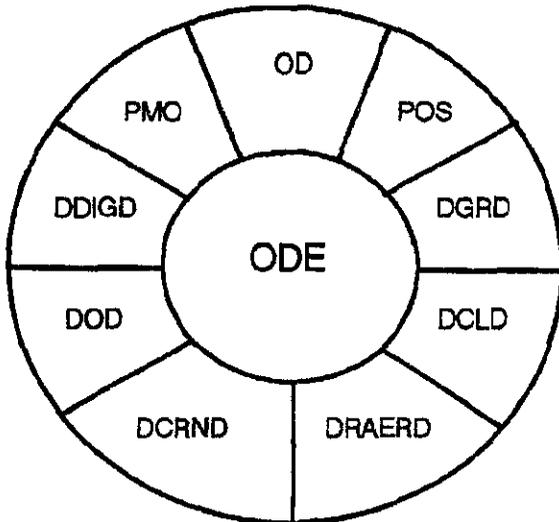
Sincerely,

David Lumia

ATTACHMENT 2

**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF DENTAL, INFECTION CONTROL, AND
GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850**

9-30-96



FROM: Viola Hibbard
DATE : September 30, 1996
NUMBER OF PAGES: 3
PHONE NO: (301) 594-1287
FAX NO: (301) 480-3002

TO: David Lumia
Excelsior Medical Corporation

FAX NO: (908) 222-2305

SUBJECT: K962938

ADDITIONAL COMMENTS: We spoke on 9/27/96 about the sterilization method for your device as compared to the predicate.

I have checked the Vital Signs sterilization method. I am unable to disclose their sterilization method because of the FOI rules. I will say that a (b) (4) [REDACTED]. Please determine how your device will be sterilized and confirm that the SAL will be 10⁻⁶. You may wish to refer to the sterilization info I have attached.

If you have questions, please call me. *[Signature]*

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510(k) STERILITY REVIEW GUIDANCE

A. PURPOSE

The purpose of this policy is to set forth the respective roles of the Office of Compliance and Surveillance (OCS) and the Office of Device Evaluation (ODE) in regard to the review of premarket notifications (510(k)s) for certain sterile devices.

B. ODE REVIEW PROCEDURES

1. STERILIZATION BY TRADITIONAL METHODS.

The following procedure applies to all 510(k)s for devices labeled as sterile and that have been sterilized by traditional methods of sterilization, i.e., steam, ETO, filtration, or radiation. Devices sterilized by other means are discussed in subsection 2, below. The following information concerning the specifications related to sterility should be collected and reviewed by ODE during the review of the 510(k) for a sterile device:

- the sterilization method that will be used;
- a description of the method that will be used to validate the sterilization cycle, but not the validation data itself;
- the sterility assurance level(SAL) for the device which the firm intends to meet;
- a description of the packaging to maintain the device's sterility(this is not to include packaging integrity testing data);
- if sterilization involves ETO, the maximum levels of residues of ethylene oxide, ethylene chlorhydrin, and ethylene glycol which remain on the device;
- whether the product is "pyrogen free" and a description of the method used to make that determination;
- the radiation dose, if radiation sterilization will be used.

Only this information will be collected regardless of how the device is labeled, i.e., whether it is labeled sterile, sterile until opened or damaged, or sterile until a stated expiration date.

PROPOSED RULES

Gas-Chromatographic Determination of Reaction Products," *Z. Analytical Chemistry*, 264(3):401-408, 1973.
 Polyethylene Glycols, pp. 628-629. Chemicals Codex, 2d Ed., National Academy of Sciences, Washington, DC, 1972.

75. Whitbourne, J. E., H. A. Mogenhan, and R. R. Ernst, "Determination of 2-Chloroethanol in Surgical Materials by Extraction and Gas Chromatography," *Journal of Pharmaceutical Sciences*, 58(8):1024-1025, 1969.

76. Maler, P. and W. Schmid, "Ten Model Mutagens Evaluated by the Micronucleus Test," *Mutation Research*, 40:325-337, 1976.

77. Friedman, M. A., and J. Staub, "Induction of Micronuclei in Mouse and Hamster Bone Marrow by Chemical Carcinogens," *Mutation Research*, 43:255-261, 1977.

78. Andersen, S. R., "Ethylene Oxide Toxicity," Presentation at the Association for the Advancement of Medical Instrumentation meeting, San Francisco, California, March 16, 1977.

79. Ramug, U. R. Gothe, and C. A. Wachtmeister, "The Mutagenicity of Chloroethylene Oxide, Chloroacetaldehyde, 2-Chloroethanol, and Chloroacetic Acid, Conceivable Metabolites of Vinyl Chloride," *Chemico-Biological Interactions*, 12:251-263, 1976.

80. Verrett, M. J., "Investigation of the Toxic and Teratogenic Effects of 2-Chloroethanol to the Developing Chick Embryo," Internal FDA memorandum to T. Balasa, March 21, 1974.

81. Courtney, K. D., and J. E. Andrews, "Teratogenic Evaluation of 2-Chloroethanol in the CD-1 Mouse," Unpublished, 12pp.

Lawrence, W. H., J. E. Turner, and J. L. "Toxicity of Ethylene Chlorohydrin to Toxicity Studies," *Journal of Pharmaceutical Sciences*, 60 (4): 568-571, 1971.

83. Geldblatt, M. W., "Toxic Effects of Ethylene Chlorohydrin," Part II: Experimental, *British Journal of Industrial Medicine*, 1:213-223, 1944.

84. Johnson, M. K., "Detoxification of Ethylene Chlorohydrin," *Food and Cosmetic Toxicology*, 5:449, 1967.

85. Hirose, T., R. Goldstein, and C. Bailey, "Hemolysis of Blood Due to Exposure to Different Types of Plastic Tubing and the Influence of Ethylene Oxide Sterilization," *Journal of Thoracic and Cardiovascular Surgery*, 45(2):245-251, 1963.

86. Clarke, C. P., W. L. Davidson, and J. B. Johnston, "Haemolysis of Blood Following Exposure to an Australian Manufactured Plastic Tubing Sterilized by Means of Ethylene Oxide Gas," *The Australian and New Zealand Journal of Surgery*, 36:53-56, 1966.

87. O'Leary, R. K. and W. L. Guess, "Toxicological Studies on Certain Medical Grade Plastics Sterilized by Ethylene Oxide," *Journal of Pharmaceutical Sciences*, 57(1): 12-17, 1968.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 505,

506, 507, 512, 513-521, 701, 52 Stat. 1049-1050, as amended, 1052-1053 as amended, 1055-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended; 82 Stat. 347-351, 90 Stat. 540-574 (21 U.S.C. 321, 351, 355, 356, 357, 360c-360k, 371)), the Public Health Service Act (sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262), and, under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

PART 221—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. By adding a new § 211.70 to Subpart C to read as follows:

§ 211.70 Maximum residue limits and maximum daily levels of exposure for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

(a) Residue limits: Each drug product of a type listed in this paragraph for which ethylene oxide is used as a sterilant in the manufacture of the finished product, its components, or its market container shall not, when tested as packaged in its market container, exceed the following residue levels:

Drug product	Ethylene oxide	Ethylene chlorohydrin	Ethylene glycol
Ophthalmics (for topical use)	10	20	60
Injectables (including veterinary intramuscular infusions)	10	10	30
Intrauterine device (containing a drug)	5	10	10
Surgical scrub sponges (containing a drug)	25	250	500
Hard gelatin capsule shells	25	25	25

(b) Each drug product shall conform to the limits set forth in paragraph (a) of this section during the shelf life of the product.

(c) Any drug product falling to comply with the requirements of paragraphs (a) and (b) of this section shall not be released for marketing.

(d) Each manufacturer of a drug product subject to this section shall prepare a residue dissipation curve for each manufacturing procedure in which ethylene oxide is used as a sterilant for the drug product, its components, or its market container.

(e) Each drug product intended to be reconstituted or diluted prior to dispensing, or use, shall conform to the limits set forth in paragraph (a) of this section as reconstituted or diluted.

(f) Daily exposure levels: the maximum daily level of exposure to resi-

dues of ethylene oxide and its reaction products from any drug product subject to paragraph (a) of this section, under the conditions for use in the drug product's recommended or approved labeling, shall not exceed the following limits set:

- Ethylene oxide, 30 µg/kg/day/30 days
- Ethylene chlorohydrin, 15 µg/kg/day/30 days
- Ethylene glycol, 2.5 mg/kg/day/30 days

A product which complies with paragraph (a) of this section shall also comply with the limits set forth in this paragraph:

PART 821—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES; STERILE DEVICES

2. By adding a new Part 821 consisting of one section to read as follows:

Sec. 821.100 Maximum residue limits for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

Authority: Secs. 513-521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 540-574 (21 U.S.C. 360c-360k, 371).

§ 821.100 Maximum residue limits for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

(a) Each medical device for human use of a type listed in this paragraph for which ethylene oxide is used as a sterilant in the manufacture of the finished device, its component parts, or its market container shall not, when tested as packaged in its market container, exceed the following residue levels:

Medical device	Ethylene oxide	Ethylene chlorohydrin	Ethylene glycol
Implant:			
Small (< 10 grams)	250	250	5,000
Medium (10-100 grams)	100	100	2,000
Large (> 100 grams)	25	25	500
Intrauterine device	5	10	10
Intraocular lenses	25	25	500
Devices contacting mucosa	250	250	5,000
Devices contacting blood (ex vivo)	25	25	250
Devices contacting skin	150	250	5,000
Surgical scrub sponges	25	250	500

(b) Any medical device for human use falling to comply with the requirements of paragraph (a) of this section shall not be released for marketing.

(c) Each manufacturer of a medical device for human use subject to this section shall prepare a residue dissipation curve for each manufacturing procedure in which ethylene oxide is used as a sterilant for the device, its component parts, or its market container.

ATTACHMENT 3

Summary of Telephone Conversations

Date: (b) (4)

To: (b) (4)

From: (b) (4)

Summary of Discussion regarding K962938:

(b) (4)

(b) (4)

ATTACHMENT 4



OCT 25 1996

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850ATTACHMENT
NO.4

Mr. David Lumia
President
Excelsior Medical Corporation
P.O. Box 299
Long Branch, New Jersey 07740-0299

Re: K962938
Trade Name: Excelsior Disposable Syringe W/Normal Saline
(.9% Sodium Chloride)
Regulatory Class: II
Product Code: FOZ
Dated: July 23, 1996
Received: July 29, 1996

Dear Mr. Lumia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

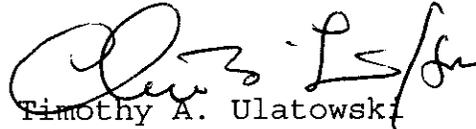
Page 2 - Mr. Lumia

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Timothy A. Ulatowski
Acting Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 5



**PERFORMANCE QUALIFICATION
OF THE**

(b) (4)

(b) (4)

**1923 Heck Avenue
Neptune, NJ 07753**



**PROTOCOL
NUMBER:**

(b) (4)

Page 1 of 10

V A L I D A T I O N P R O T O C O L

TITLE: PERFORMANCE QUALIFICATION OF THE (b) (4)

ISSUE DATE:

(b) (4)

**PROTOCOL NUMBER:
VERSION NUMBER:
ISSUE DATE:**

(b) (4)



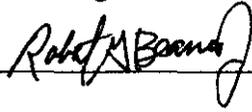
Protocol Number:
Issue Date:
Version Number:

(b) (4)

TITLE: Performance Qualification of the (b) (4)

PERFORMANCE QUALIFICATION PROTOCOL

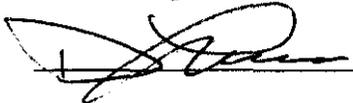
PQ PROTOCOL NO. (b) (4)

	Name	Signature	Date
Author	Robert G Beane Jr		12/1/99

INITIAL APPROVAL

The initial approval of the PQ protocol shall be the responsibility of Excelsior Medical Corporation:

Excelsior Medical Corporation

	Name	Signature	Date
President	David Lumia		12/1/99



Protocol Number:
Issue Date:
Version Number:

(b) (4)

TITLE: Performance Qualification of the ETC Autoclave

TABLE OF CONTENTS

- 1.0 PERFORMANCE QUALIFICATION OBJECTIVE**
- 2.0 SCOPE**
- 3.0 GENERAL DESCRIPTION**
- 4.0 RESPONSIBILITIES**
- 5.0 PERFORMANCE QUALIFICATION**
 - 5.1 METHODOLOGY
 - 5.2 PROCEDURES
 - 5.3 APPENDICES DESCRIPTION
 - 5.4 ACCEPTANCE CRITERIA
- 6.0 FINAL REPORT AND APPROVAL**
- 7.0 PQ APPENDICES AND ATTACHMENTS**



Protocol Number: (b) (4)
Issue Date:
Version Number:

TITLE: Performance Qualification of the ETC Autoclave

1.0 PERFORMANCE QUALIFICATION OBJECTIVE

The Performance Qualification (PQ) is a formal process, which documents that the (b) (4) performs according to design specification, manufacturers' criteria and the requirements of Excelsior Medical Corporation. The PQ protocol also defines the qualification requirements and the acceptance criteria required for the completion of the qualification process.

2.0 SCOPE

The scope of this validation protocol is limited to the Performance Qualification of the ETC Autoclave, Equipment Identification No. (b) (4)

3.0 GENERAL DESCRIPTION

The (b) (4), Equipment Identification No. (b) (4)

The chamber and roller locking doors are all controlled from the control system box, which contains the CPU, interface panel, printer, and power supply. This autoclave is used to sterilize Excelsior Medical Corporation products and assure sterility assurance levels.

4.0 RESPONSIBILITIES

The responsibility for the preparation of the protocol and report documentation; execution of the protocol; and review of the information, is broken down as follows:

4.1 Excelsior Medical Corporation

- 4.1.1 Final approval of the PQ protocol; the qualification data documents; and the final report.
- 4.1.2 Supplying all procedures, data, manuals and documentation necessary for the generation and completion of the protocol.
- 4.1.3 Delivery of the systems in complete working order, calibrated and fully operational.
- 4.1.4 Supplying the Biological Indicators necessary for the protocol.



Protocol Number: (b) (4)
Issue Date:
Version Number:

TITLE: Performance Qualification of the (b) (4)

5.0 PERFORMANCE QUALIFICATION

5.1 METHODOLOGY

The performance of the (b) (4) during normal operation will be verified and documented as outlined in Datasheet (b) (4). The PQ appendix will define its objectives and provide an input form for recording the appropriate information. The information contained within this PQ will be utilized to demonstrate that the (b) (4) and associated instruments if operated according to established procedures will produce consistent results.

5.1.1 References

5.1.1.1 Operations and Maintenance Manual cGMP (b) (4)

5.2 PROCEDURE

Process equipment and validation test equipment/materials must be calibrated prior to executing the qualification tests.

Deviations, exemptions, and significant observations are to be noted in the "Comments" section at the bottom of the Datasheet. Include action taken or justification of acceptance.

When executing the system performance test program, the system is to be operated according to the most recent available version of its operational SOP.

5.2.1 EQUIPMENT AND TESTING MATERIALS

- 5.2.1.1 (b) (4)
- 5.2.1.2
- 5.2.1.3
- 5.2.1.4
- 5.2.1.5



Protocol Number: (b) (4)
Issue Date:
Version Number:

TITLE: Performance Qualification of the (b) (4)

5.2.2 KAYE VALIDATOR 2000 PROGRAMMING

5.2.2.1 (b) (4)
5.2.2.2 (b) (4)

5.2.3 (b) (4) CALIBRATION PROCEDURE

5.2.3.1 (b) (4) will be calibrated using the automatic calibration programmed function supplied with the (b) (4). The TCs will be calibrated at (b) (4) as the high temperature calibration point and (b) (4) as the midpoint, using a NIST (National Institute of Standards and Technology) traceable RTD (b) (4) temperature reference bank. (b) (4) recommended calibration criteria will be applied and printed.

5.2.3.2 Upon completion of the three test functions, the TC wire will undergo post calibration verification at (b) (4) according to the (b) (4) Post Calibration Program.

5.2.3.3 After the post calibration verification, the calibration report will be printed along with the post calibration verification report.

5.2.4 LOAD CHAMBER PENETRATION TEST

The loaded chamber penetration test will demonstrate that the product/materials held in the (b) (4) are consistently exposed to sufficient (b) (4). Three (3) runs will be performed.



Protocol Number:
Issue Date:
Version Number:

(b) (4)

TITLE: Performance Qualification of the ETC Autoclave

5.2.4.1 Test Procedure

- a) The representative load for the (b) (4) is defined in Appendix A.
- b) Prepare the load diagram, including locations of all thermocouples.
- c) Position ten (10) penetration (b) (4) in the chamber within the components/materials. The probed containers should be distributed uniformly throughout the load. Additionally, one (1) (b) (4) should be placed in each of the exhaust drains. Biological Indicators will be distributed throughout the load at the location of each load thermocouple.
- d) Initiate the appropriate Autoclave cycle.
- e) Reset the (b) (4) at the beginning of the sterilization cycle and record the temperature every (b) (4).
- f) The minimum, maximum and average temperatures as well as overall thermocouple range and F₀ values for each (b) (4) will be included in the final report along with a printout of the data. Biological Indicator data will also be reported in the final report.

5.3 APPENDIX DESCRIPTIONS

5.3.1 Appendix A: (b) (4) Datasheet

- 5.3.1.1 Bio Indicator Definition Datasheet
- 5.3.1.2 (b) (4) Description Datasheet
- 5.3.1.3 (b) (4) Diagram
- 5.3.1.4 Temperature Results Datasheet
- 5.3.1.5 Biological Indicator Results Datasheet



Protocol Number: (b) (4)
Issue Date:
Version Number:

TITLE: Performance Qualification of the ETC Autoclave

5.3 ACCEPTANCE CRITERIA

The Performance Qualification must demonstrate that the system operates in accordance with the following specific acceptance criteria.

- 5.4.1 If any (b) (4) does not meet the criteria of (b) (4) of the post calibration verification (b) (4), the calibration procedure must be repeated.
- 5.4.2 All Bio Indicator results should confirm that the (b) (4) environment is sterile (negative). A positive control from the same lot number should be proven to be active (positive).
- 5.4.3 Each (b) (4) must reach an (b) (4) value of (b) (4).
- 5.4.4 At the completion of the triplicate runs for each load, a maximum allowance of (b) (4) since previous verification will be excluded from data analyses. (b) (4) will be considered valid.

6.0 FINAL REPORT AND APPROVAL

Following completion of the overall protocol requirements, a final report will be generated documenting any discrepancies between the design and operating requirements and the actual performance of the (b) (4). Any inconsistencies in the procedures noted during the execution of the PQ Protocol will be addressed. Upon satisfactory completion of the protocol and the final report, the designated reviewers will examine all of the appendices and attachments and certify that the equipment/system is acceptable from a performance standpoint.

7.0 PQ APPENDICES AND ATTACHMENTS

The Datasheets provided in Appendix A, are designed to carry out the stated protocol Performance Qualification objective.



Protocol Number: (b) (4)
Issue Date: (b) (4)
Version Number: (b) (4)

TITLE: Performance Qualification of the (b) (4)

DISPOSITION OF NON-CONFORMING DATA

PQ PROTOCOL NO. (b) (4)

Explain the nature of the non-conforming data and the acceptability or the action required to resolve the discrepancy.

NATURE OF NON-CONFORMING DATA:

The performance testing of the Installation and Operation Qualification of the (b) (4)

DISPOSTION:

The (b) (4), Equipment Identification Number (b) (4), met acceptance criteria, though the empty chamber temperature distribution test conducted within the Operational Qualification is currently being investigated.

Completed by: Rodney Brandy Date: 12/1/99

Reviewed by: [Signature] Date: 12/1/99



Protocol Number: (b) (4)
Issue Date:
Version Number:

TITLE: Performance Qualification of the (b) (4)

PQ PROTOCOL FINAL REPORT

PQ PROTOCOL NO. (b) (4)

The acceptance criteria specified within this Performance Qualification (PQ) have been satisfied with no unexplained discrepancies. All discrepancies found during the PQ have been identified and described on the "Disposition of Non-Conforming Data" form and attached to this report.

The PQ for the (b) (4), Equipment Identification No. (b) (4), was examined and found to be acceptable as defined in the qualification requirements for this equipment.

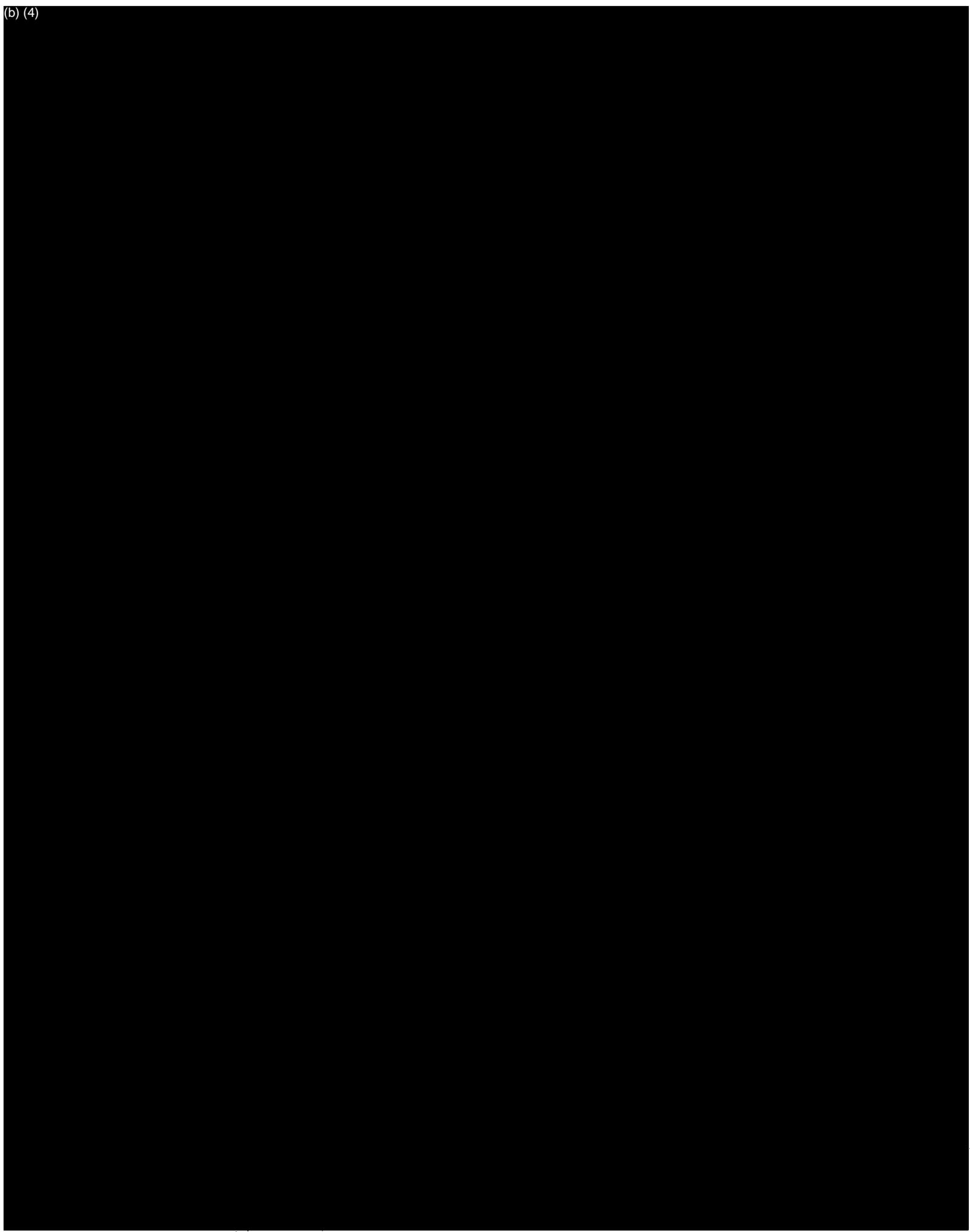
We here by certify that the ETC Autoclave, Equipment Identification No. (b) (4), is acceptably qualified.

FINAL APPROVAL

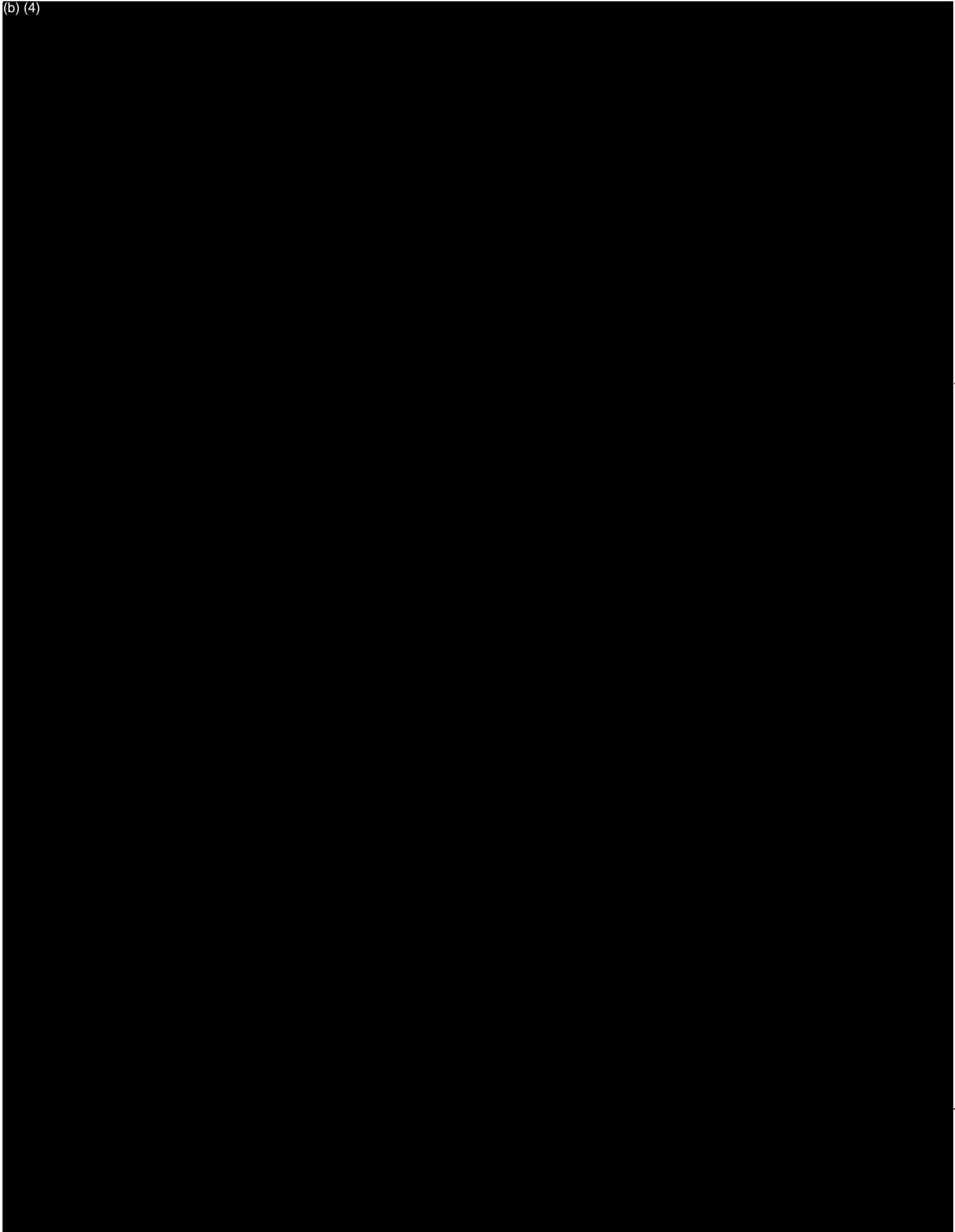
The final approval of the PQ protocol for the system/equipment designated above has been reviewed and approved by Excelsior Medical Corporation:

	Name	Signature	Date
President	David Lumia		11/99

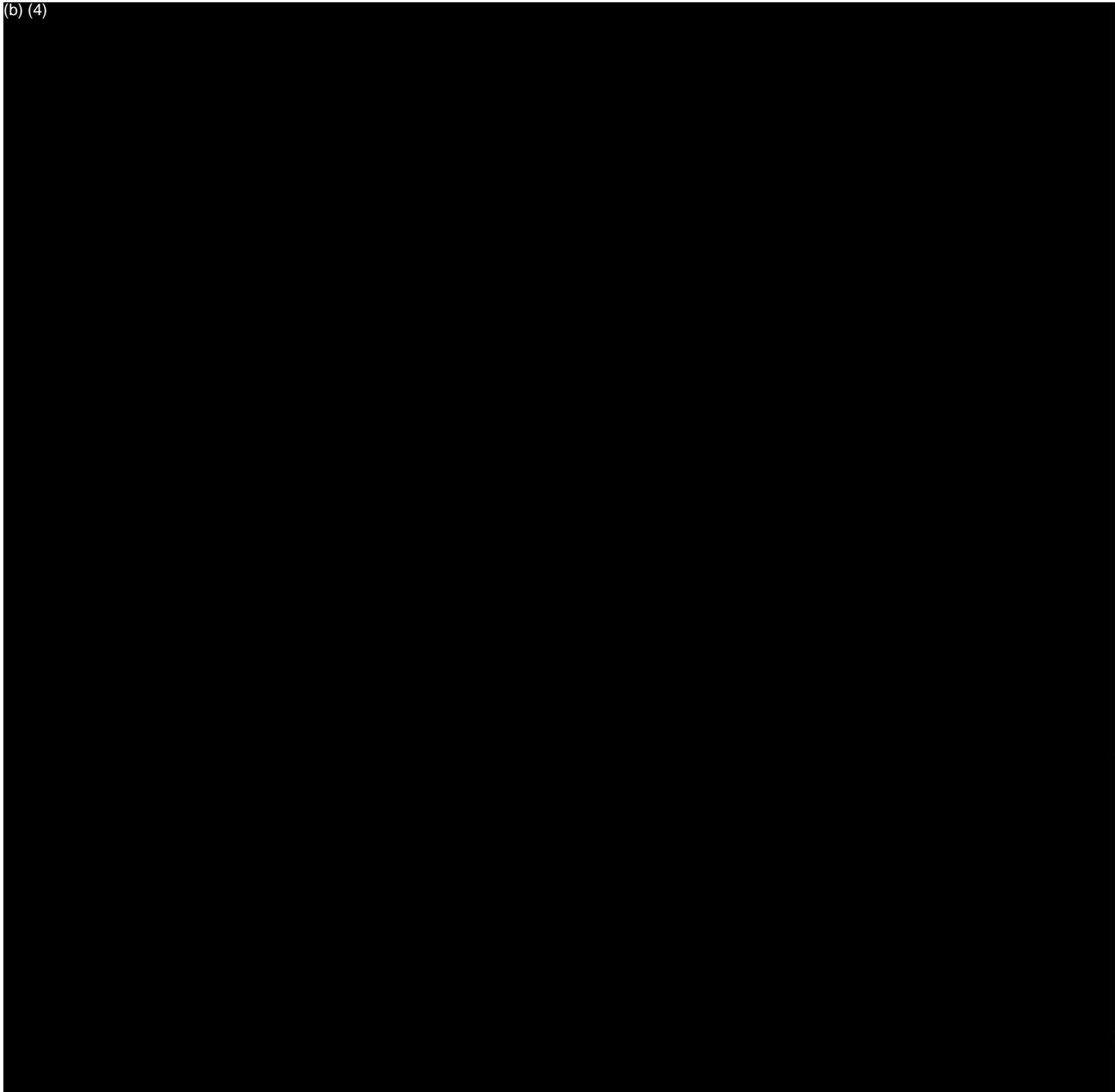
ATTACHMENT 6



40



2025 RELEASE UNDER E.O. 14176





December 14, 2000

Diane B. Radice, Compliance Officer
Food and Drug Administration
10 Waterview Blvd.
Parsippany, NJ 07054

Dear Ms. Radice:

I am in receipt of the (b) (4)

I request an extension of time to the end of next week to address all of the issues listed in the letter.

(b) (4)

Please call me if this request is a problem. Otherwise, I will respond to the letter in writing by the end of next week.

Sincerely,

A handwritten signature in black ink, appearing to read "David Lumia", written over a horizontal line.

David Lumia, President

December 22, 2000

Diane B. Radice, Compliance Officer
Food and Drug Administration
10 Waterview Blvd.
Parsippany, NJ 07054

Dear Ms. Radice:

(b) (4)

Item 1

a)

(b) (4)

b)

(b) (4)

6

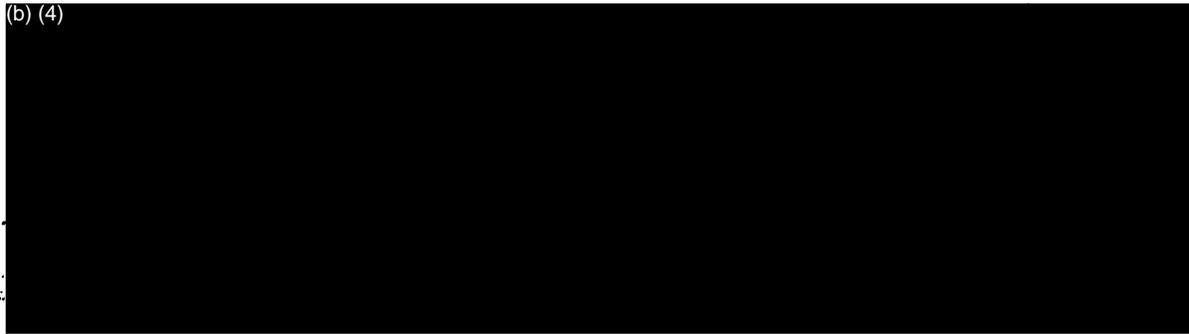
(b) (4)

c) (b) (4)

d) (b) (4)

Item 2

(b) (4)



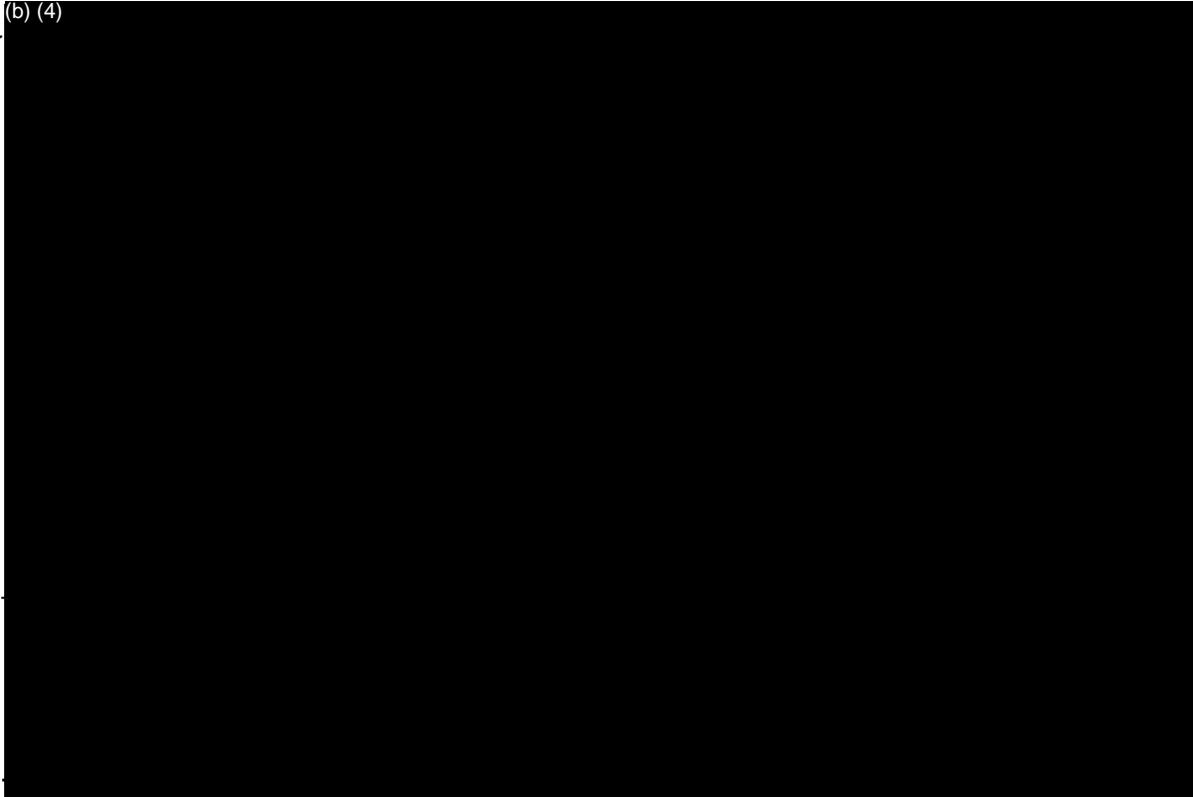
Item 3

(b) (4)



Item 4

(b) (4)





(b) (4)

[Redacted]

Item 5

(b) (4)

[Redacted]

Item 6

(b) (4)

[Redacted]

Item 7

(b) (4)

[Redacted]

FOIA(b)(7) - Exemption from disclosure of information that is withheld from public release because it is exempt from disclosure under this law.

(b) (4)



Additional Comments (page 3 of your letter)

(b) (4)



Sincerely,

David Lumia, President

Approved for release by NSA on 05-08-2014 pursuant to E.O. 13526



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

January 29, 2001

Mr. David Lumia
President
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 07753

Dear Mr. Lumia:

This letter will acknowledge receipt of your response dated December 22, 2000. (b) (4)

[Redacted]

(b) (4)
[Redacted]

- (b) (4)
[Redacted]

(b) (4)

A large rectangular area of the document is completely redacted with black ink. The redaction covers approximately the top half of the page's content.

(b) (4)

A single line of text is redacted with black ink. The redaction covers the entire width of the line.

Sincerely,

A handwritten signature in cursive script, appearing to read "Diane B. Radice".

DIANE B. RADICE
Compliance Officer
New Jersey District

March 9, 2001

Diane B. Radice, Compliance Officer
Food and Drug Administration
10 Waterview Blvd.
Parsippany, NJ 07054

Dear Ms. Radice:

This letter is in response to your letter dated January 29, 2001. (b) (4)

[Redacted]

(b) (4)

1. (b) (4)

2. (b) (4)

3. (b) (4)

4. (b) (4)

5. (b) (4)

6. (b) (4)



Please contact me if you have any questions or comments.

Sincerely,

David Lumia, President

ATTACHMENT 7



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6006

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

March 16, 2001

Mr. David Lumia
President
Excelsior Medical Corporation
1923 Heck Avenue
Neptune, NJ 07753

Dear Mr. Lumia:

This letter will acknowledge receipt of your response dated March 9, 2001. (b) (4)

[Redacted]

If you have any further questions, please feel free to contact me at the number listed above.

Sincerely,

Diane B. Radice

DIANE B. RADICE
Compliance Officer
New Jersey District

ATTACHMENT 8

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities: To the best of my knowledge, the verification and validation activities for the modifications as identified in the **Summary of Design Control Activities** section of the Cover Letter were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Ruben Martinez, Regulatory/Quality

11-27-05

Date

Manufacturer:

With regard to the Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes, the manufacturer, Excelsior Medical Corporation, 1923 Heck Avenue, Neptune, NJ 07753, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Ruben Martinez, Regulatory/Quality

11-27-05

Date

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities: To the best of my knowledge, the verification and validation activities for the modifications as identified in the **Summary of Design Control Activities** section of the Cover Letter were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Ruben Martinez, Regulatory/Quality

11-27-05

Date

Manufacturer: With regard to the Excelsior Sterile Field Saline Flush and Heparin Lock Flush Syringes, the manufacturer, Excelsior Medical Corporation, 1923 Heck Avenue, Neptune, NJ 07753, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Ruben Martinez, Regulatory/Quality

11-27-05

Date