

K140133

**MAY 15 2014**

**Section 5. 510(k) Summary**

**K Number** \_\_\_\_\_

**Submission Date:** January 16, 2014

**General Information**

Classification	Class II
Trade Name	Infuset™ Flow Control Extension Set
Common Name:	I.V. Flow Controller

**Classification Name and Reference:**

Intravascular Administration Set  
21 CFR §880.5440

**Submitter**

Peter Kollings  
EMED Technologies Corporation  
1264 Hawks Flight Ct., Ste. 200  
El Dorado Hills, Ca 95762  
Tel: 916.932.0071 x114  
Fax: 916.932.0074

**Intended Use**

Infuset™ Flow Control Extension Sets are intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

**Predicate Device(s)**

Freedom 60 Syringe Infusion Pump System (K933652)

**Device Description**

EMED Infuset™ Flow Control Extension Sets are disposable devices allowing users to obtain a controlled and precise rate of fluid flow when used with the RMS Freedom 60 Syringe Infusion Pump System.

Each Infuset™ Flow Control Extension Sets consist of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources

compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset™ Flow Control Extension Sets rely upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

**Materials and Characteristics**

Infuset™ Flow Control Extension Sets are equivalent in performance, physical properties, using similar materials, and having the same indications for use as the predicate. Therefore no new issues of safety or effectiveness are introduced by the minimal differences in design.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED Infuset™ Flow Control Extension Sets and the predicate.

**Table 5-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.
Material	PVC	PVC
Design – Lengths	7.5 cm - 97 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

**Performance**

Table 5-2 below summarizes testing results performed to establish conformance of the Infuset™ Flow Control Extension Sets to internal product specifications and requirements, as well as equivalence to the predicate device.

**Table 5-2**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Flow Rate Control (0.9% saline at 20-23°C, with Freedom60)	Range: 202-2244 ml/hr  Precision Less than 5% RSD  Accuracy: +/- 10%	Range: 47 - 1743 ml/hr  Precision Less than 5% RSD  Accuracy: -27% to + 38%
Pressure	Not Less than 25 psi	Not Less than 15 psi

The outcomes of these tests further indicate that the Infuset™ Flow Control Extension Set is substantially equivalent to the predicate accessory in performance, effectiveness, and safety.

### **Biocompatibility**

In accordance with ISO 10993-1:2009 and based on the intended use of the Infuset™ Flow Control Extension Sets, studies were performed including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

**Table 5-3**

<b>Standard</b>	<b>Test Name</b>	<b>Test Result</b>	<b>Other Name</b>
ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
ISO 10993-10	Sensitization	Pass	Kligman Maximization
ISO 10993-10	Irritation	Pass	Intracutaneous Injection
ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
ISO 10993-11	Pyrogenicity	Pass	Rabbit Pyrogen
ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Thromboplastin Time
ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)
USP <85>	LAL Endotoxin Test	Pass	LAL Endotoxin Quantitation Test (Kinetic-QCL Method)

### **Sterility, Shelf-life, and Packaging**

The Infuset™ Flow Control Extension Sets will be sterilized to a sterility assurance level (SAL) of  $10^{-6}$  and with a shelf life of 5 years.

### **Summary of Substantial Equivalence**

EMED Technologies Corporation Infuset™ Flow Control Extension Sets are substantially equivalent to the commercially available predicate device accessory in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Differences between the EMED Infuset™ Flow Control Extension Sets and the predicate do not raise any new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 15, 2014

EMED Technologies Corporation  
Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
1264 Hawks Flight Ct., Ste. 200  
El Dorado Hills, CA 95762

Re: K140133

Trade/Device Name: Infuset Flow Control Extension Set  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular administration set  
Regulatory Class: Class II  
Product Code: FPA  
Dated: April 11, 2014  
Received: April 15, 2014

Dear Mr. Kollings:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Page 2 – Mr. Kollings

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mary S. Runner -S

Erin I. Keith, M.S.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)  
K140133

Device Name  
Infuset™ Flow Control Extension Set

*Indications for Use (Describe)*

The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a contained to a patient's vascular system.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)       Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C. Chapman  
Date: 2014.05.15 11:50:03 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

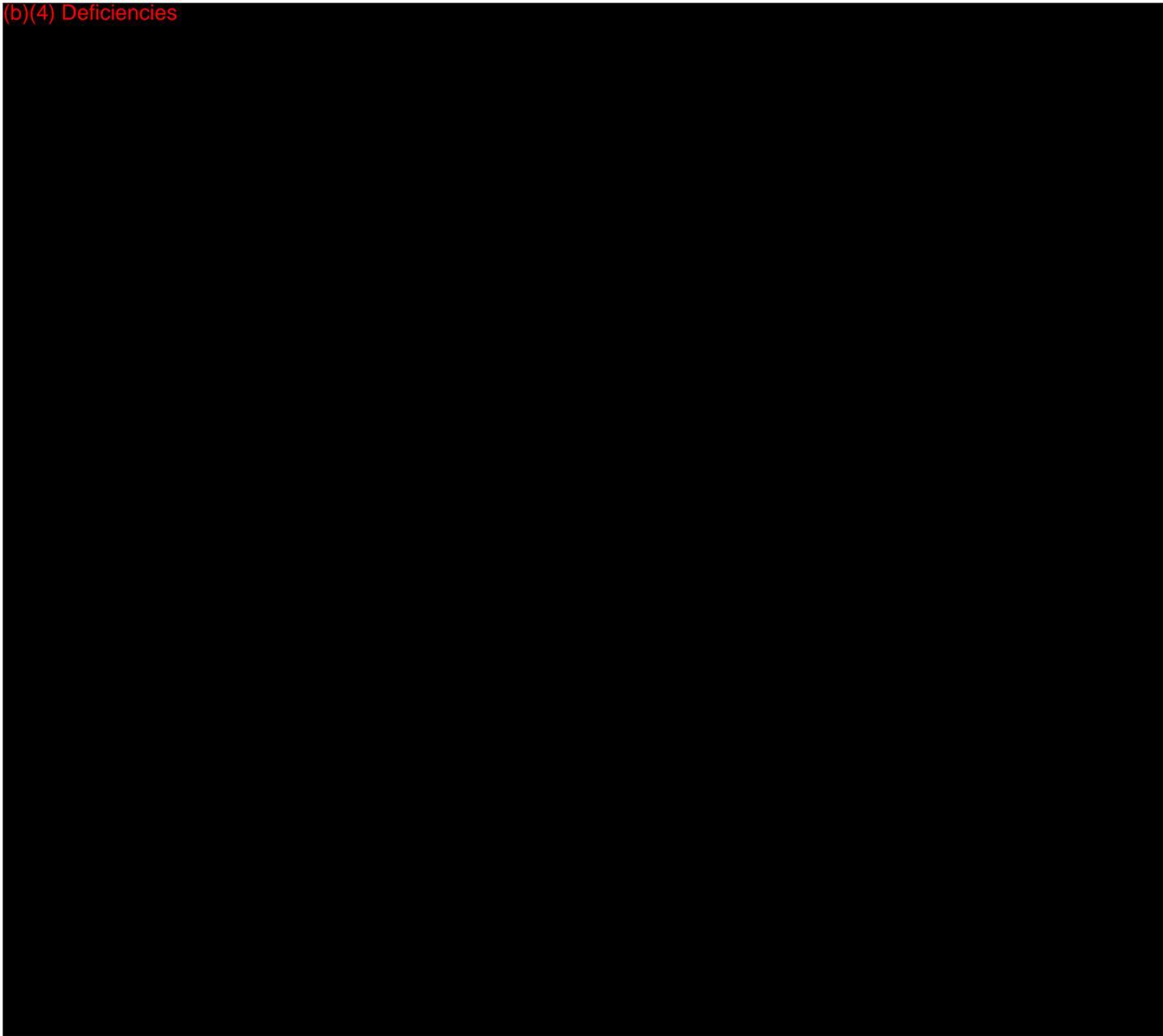
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PRAStaff@fda.hhs.gov

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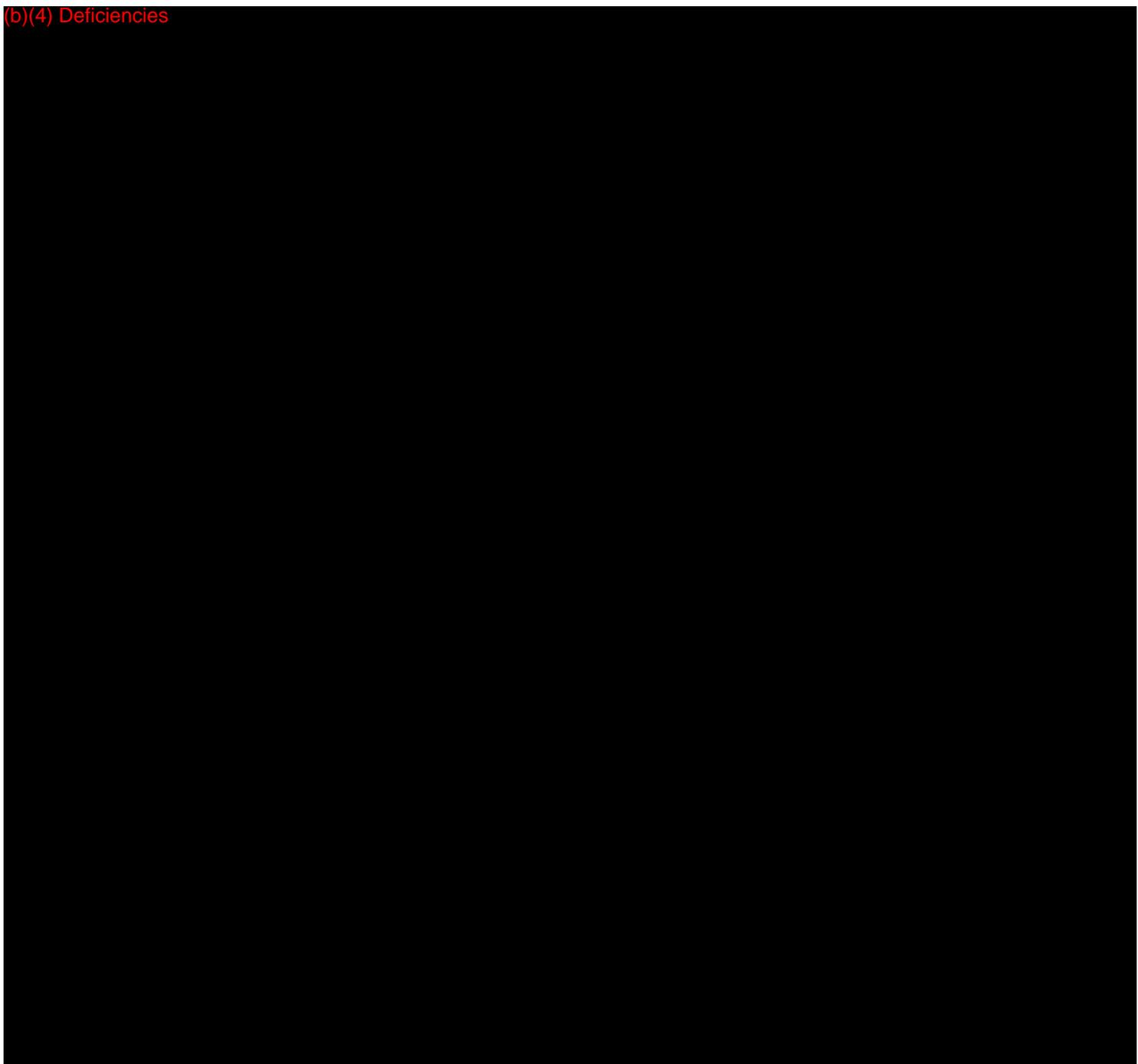
Dear Nick,

I have completed the review of K140133 biocompatibility. I wish to talk to you on the Deficiency 1. Please let me know your availability tomorrow. With the rest of the deficiencies, if you have any concerns, please let me know as well.

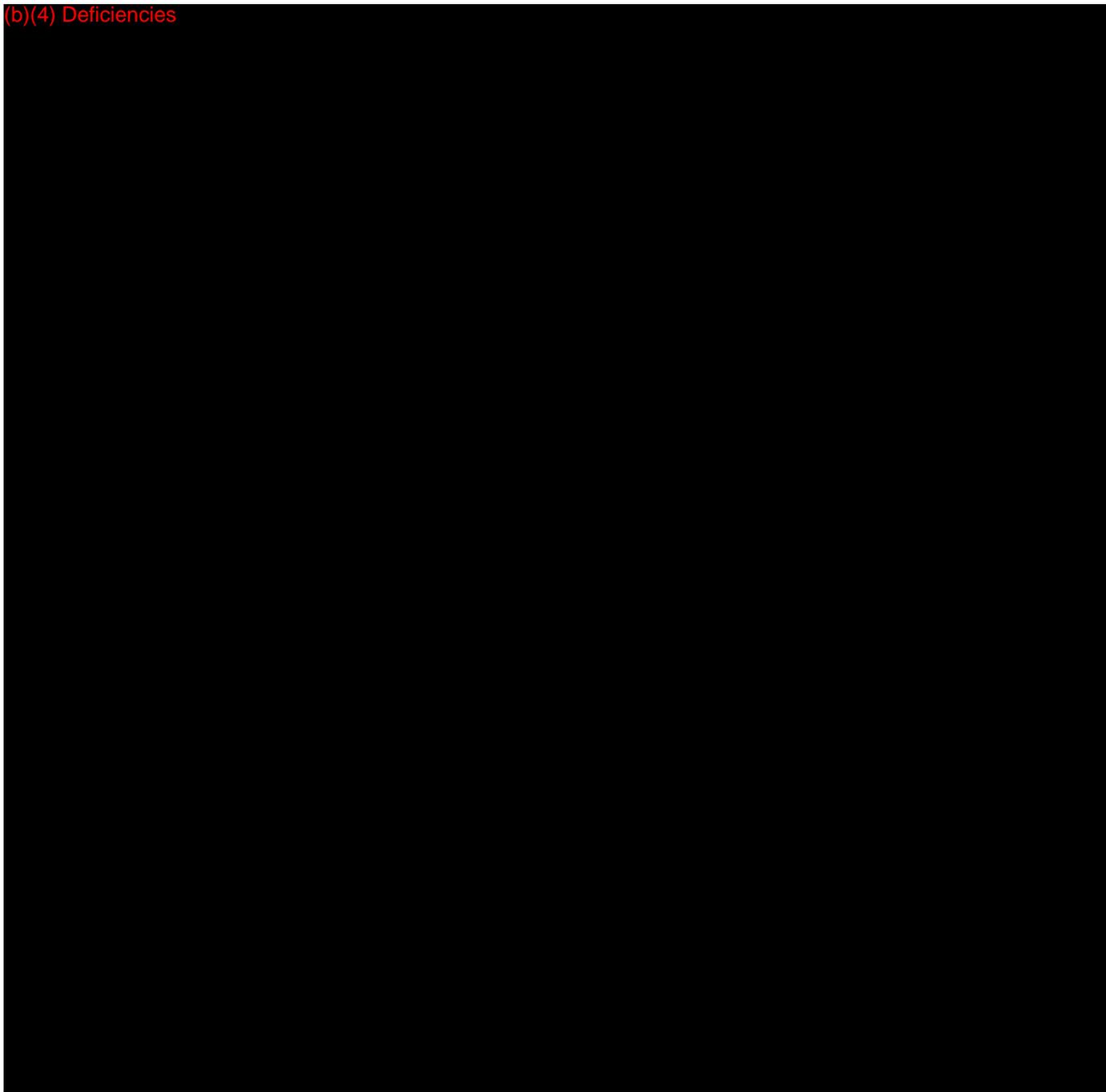
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(b)(4) Deficiencies



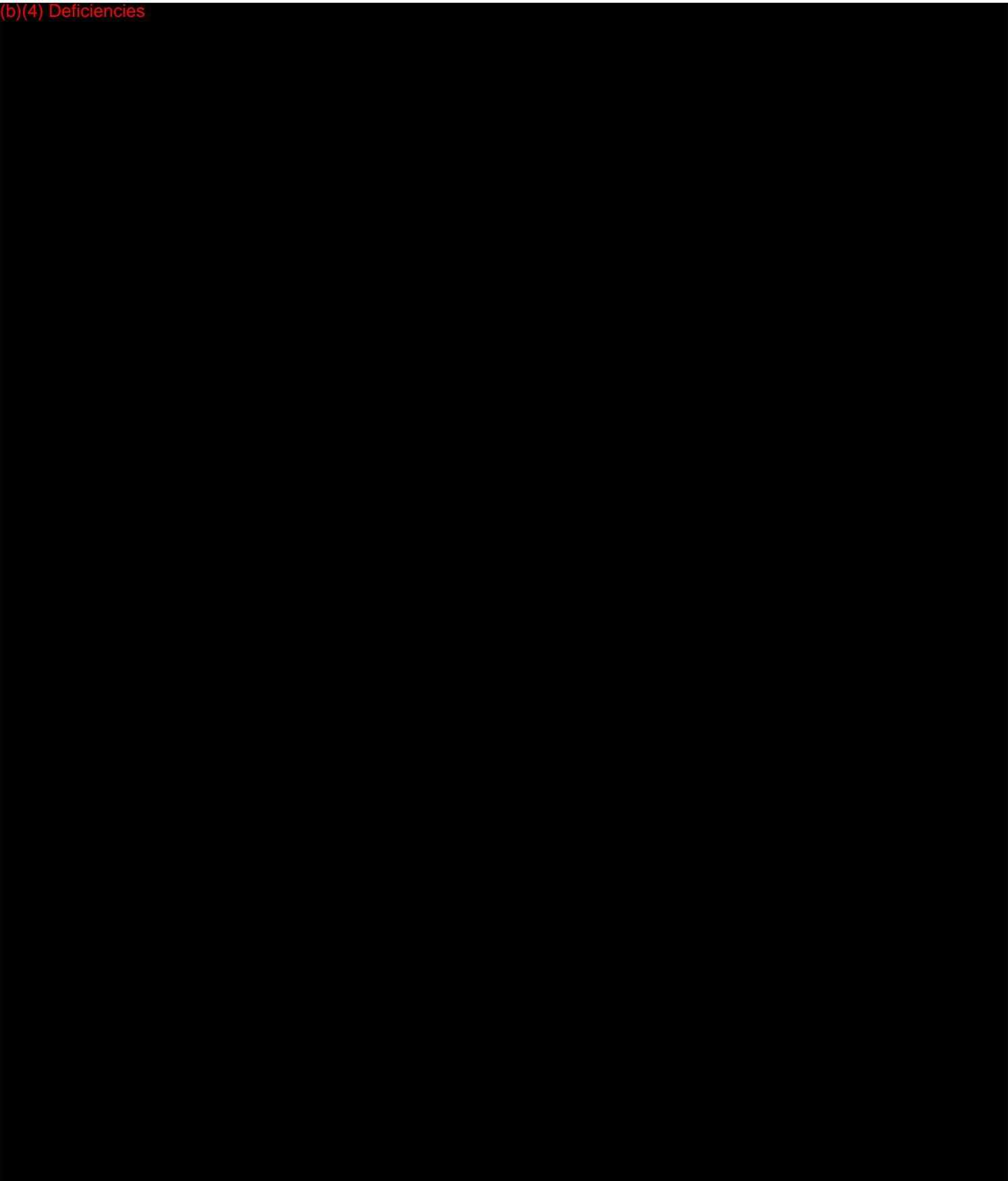
(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies



Thanks,

Rakhi

***Rakhi M. Dalal, Ph.D.***, Toxicologist & Team Leader (Biocompatibility)

CDRH Nanotechnology Reviewer Network (NRN), Chair

General Hospital Devices Branch

Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices

Office of Device Evaluation, Center for Devices and Radiological Health

U.S. Food and Drug Administration

WO 66, Room 1518

10903 New Hampshire Avenue

Silver Spring, MD 20993

Tel: 301 796 6418 (tel)

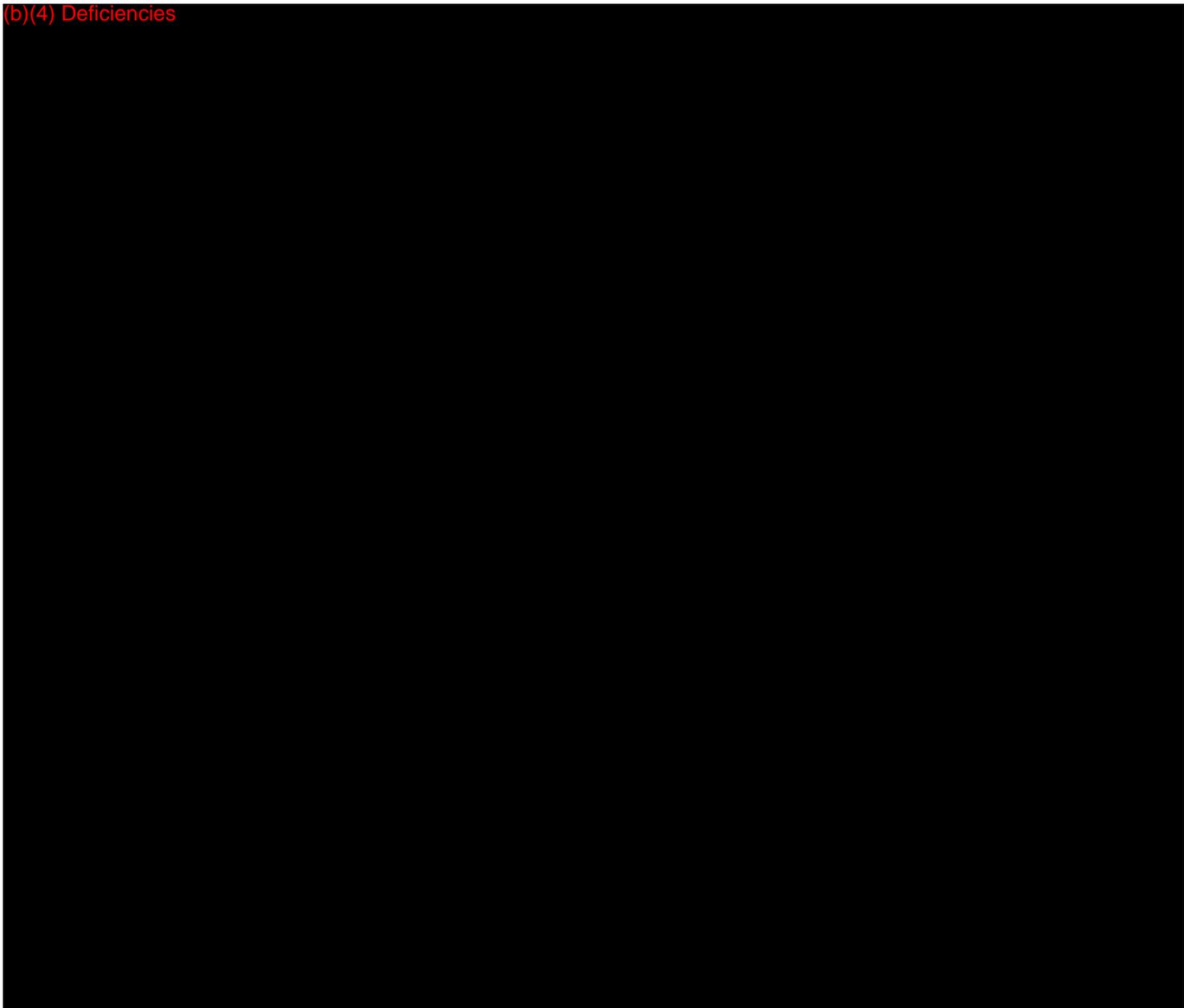
[rakhi.dalal@fda.hhs.gov](mailto:rakhi.dalal@fda.hhs.gov)

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

THIS MESSAGE 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 LAW. If you are not the intended recipient, you are hereby notified that any disclosure, dissemination, distribution, copying, or other action based on the content of this communication is NOT AUTHORIZED. If you have received this document in error, please immediately notify us by email or telephone found above.

Additional Clarification:

(b)(4) Deficiencies



CDRH DMC  
JAN 22 2014  
Received  
K140133

January 21, 2014

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Re: *Infuset™ Flow Control Extension Set (K140133) - Replacement eCopy***

The attached CD contains a replacement eCopy of K140133, *Infuset™ Flow Control Extension Set*. The included replacement eCopy is an exact duplicate of the paper copy dated January 16, 2014 and received by the Document Mail Center on January 17, 2014. The naming conventions of the files found on the replacement eCopy now comply with the eCopy guidance.

Please contact the undersigned at your earliest convenience if there are any questions regarding the information or replacement eCopy provided.

Regards,



Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

K140133

FDA CDRH DMC  
JAN 17 2014  
Received

January 16, 2014

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Re: 510(k) Premarket Notification  
TRADITIONAL**

**Infuset™ Flow Control Extension Set**

EMED Technologies Corporation is submitting the enclosed application for Infuset™ Flow Control Extension Sets that are intended to be used with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

We consider our intent to market these devices as confidential commercial information and request that FDA consider it as such.

The submission and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

If you have any questions regarding this 510(k) submission, please contact the undersigned at your earliest convenience.

**Administrative Information**

Proprietary Name: Infuset™ Flow Control Extension Set

Common Name: I.V. Flow Controller

Classification Name and Reference:

Intravascular Administration Set  
21 CFR §880.5440

Intended Use: The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

Proposed Regulatory Class: Class II

FDA Panel: General Hospital

Device Product Code: FPA

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## Design and Use of the Device

The Infuset™ Flow Control Extension Set consists of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset relies upon the properties inherent to the static fluid path dimensions dictated by the Infuset length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

Table 3-1 below provides additional detail regarding the Infuset™ Flow Control Extension Set.

**Table 3-1**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X



The power of creative thinking

Thank you for your review of this application.

Regards,

A handwritten signature in blue ink that reads "Peter Kollings".

Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

**510 (k) Premarket Notification – Traditional**

*Infuset<sup>TM</sup> Flow Control Extension Set*

**Applicant:** EMED Technologies Corporation  
Peter Kollings  
Quality Manager  
1264 Hawks Flight Ct. Ste. 200  
El Dorado Hills, Ca 95762  
Phone: 916.632.0071 x114  
Fax: 916.932.0074  
[pkollings@emedtc.com](mailto:pkollings@emedtc.com)

**Submission Date: January 16, 2014**

This submission contains CONFIDENTIAL material and information and should be restricted in its distribution. Do not copy without the permission of the Applicant

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**Section 1: Medical Device User Fee Cover Sheet**

This section contains the Medical Device User Fee Cover Sheet (payment identifier (b)(4) )

## Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  EMED TECHNOLOGIES CORPORATION 1264 HAWKS FLIGHT COURT, SUITE 200 EL DORADO HILLS CA 95762 US		2. CONTACT NAME Peter Kollings 2.1 E-MAIL ADDRESS pkollings@emedtc.com 2.2 TELEPHONE NUMBER (include Area code) 916-932-0071 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8533			
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: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <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) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD145167			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> for additional information)			
6. 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 <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. 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			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		07-Jan-2014	

Form FDA 3601 (01/2007)

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

**Section 2: Administrative - FDA Forms**

This section contains completed FDA forms 3674, *Certification of Compliance*, 3514, *CDRH Premarket Review Submission Coversheet*, and 3654, *Standards Data Reports for 510(k)s*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approval  
OMB No. 9010-0120  
Expiration Date: August 31, 2010.  
See OMB Statement on page 5.

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 01/16/2014	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <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	<b>PMA &amp; HDE Supplement</b> <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	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <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):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <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 EMED Technologies Corporation		Establishment Registration Number (if known) 2523167	
Division Name (if applicable)		Phone Number (including area code) ( 916 ) 932-0071	
Street Address 1264 Hawks Flight Ct, Ste. 200		FAX Number (including area code) ( 916 ) 932-0074	
City El Dorado Hills	State / Province Ca	ZIP/Postal Code 95762	Country USA
Contact Name Peter Kollings			
Contact Title Director of Regulatory Affairs and Quality Assurance		Contact E-mail Address pkollings@emedtc.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: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> 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			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					
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: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS			
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information			
1	FPA	2		3		4		<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement			
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	K933652	1	Freedom 60 Syring Infusion Pump System, Precision Flow Rate Tubing Set	1	Repro-Med Systems, Inc.				
2		2		2					
3		3		3					
4		4		4					
5		5		5					
6		6		6					

SECTION F	PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS
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Common or usual name or classification  
 I.V. Flow Controller

	Trade or Proprietary or Model Name for This Device		Model Number
1	Infuset Flow Control Extension Set	1	various based on configuration
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1		3		5	
7		9		11	12

Data Included in Submission  
 Laboratory Testing     
  Animal Trials     
  Human Trials

SECTION G	PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS
-----------	--

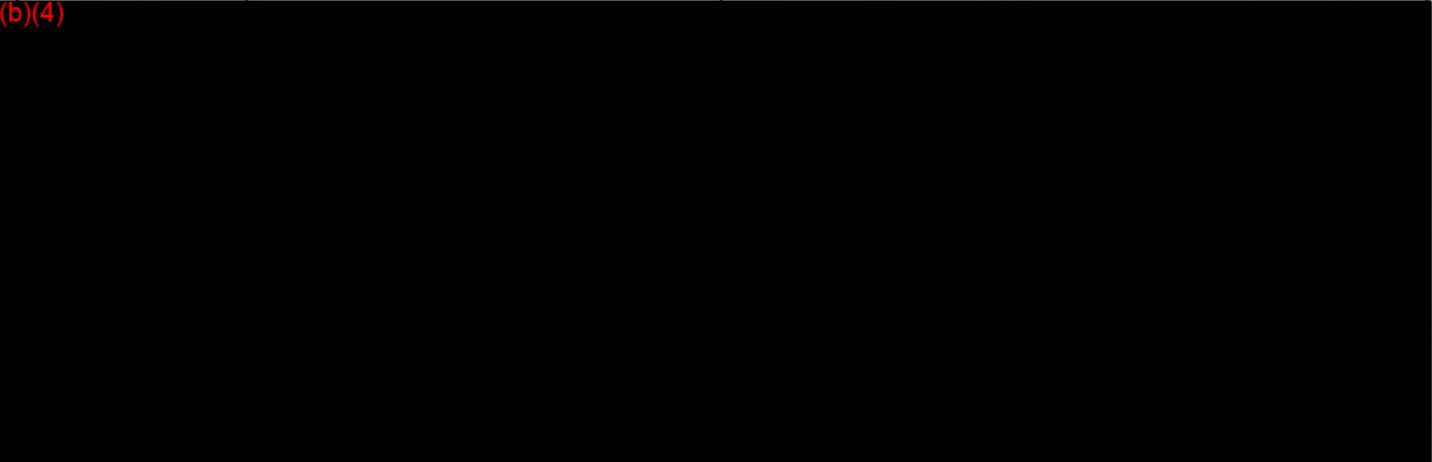
Product Code FPA	C.F.R. Section (if applicable) 21 CFR 880.5440	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital		

Indications (from labeling)  
 The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

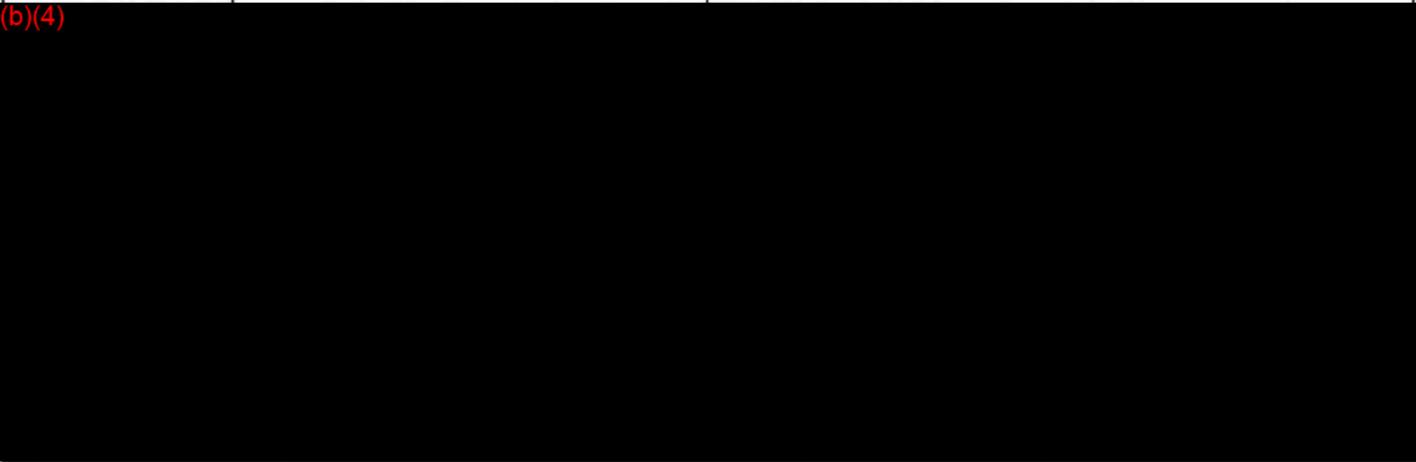
<b>Note:</b> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number <i>(if known)</i>
--	---------------------------------------

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
--	--	--	--



<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
--	--	--	---



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> (    )	
Street Address		FAX Number <i>(including area code)</i> (    )	
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	ISO 10993-7	ISO	Biological evaluation of medical devices - ethylene oxide sterilization residuals	2008	
2	ISO 11135-1	ISO	Ethylene oxide Sterilization: Requirements for development, validation and routing control of a sterilization process for medical devices	2007	
3	ISO 10993-1	ISO	Biological evaluation of medical devices - Evaluation and Testing	2009	
4	ISO 14971	ISO	Medical Devices - Application of risk management to medical devices	2007	
5	ISO 594-1	ISO	Conical Luer Fittings - General Requirements	1986	
6	ISO 594-2	ISO	Conical Luer Fittings - Lock Fittings	1998	
7	ISO 8536-8	ISO	ISO 8536-8 Infusion Equipment for medical use - infusion equipment for use with pressure infusion apparatus	2004	

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*

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 Food and Drug Administration



**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER EMED Technologies Corporation	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 01/16/2014
3. ADDRESS (Number, Street, State, and ZIP Code) 1264 Hawks Flight Ct, Ste. 200 El Dorado Hills, Ca 95762	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 916.932.0071 (Fax) 916.932.0074

**PRODUCT INFORMATION**

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)  
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)  
 (Attach extra pages as necessary)

Infuset Flow Control Extension Set

Infuset Extension Set

Infuset

**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND    NDA    ANDA    BLA    PMA    HDE    510(k)    PDP    Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): \_\_\_\_\_

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.  
**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) Peter Kollings (Title) Director of Regulatory Affairs and Quality Assurance
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 1264 Hawks Flight Ct, Ste. 200 El Dorado Hills, Ca 95762	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 916.932.0071 x 114 (Fax) 916.932.0074
	15. DATE OF CERTIFICATION 01/16/2014

**Instructions for Completion of Form FDA 3674**

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.
9. **Certification** - This section contains three different check-off boxes.  
**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.  
**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.  
**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
Form No. FDA 3674  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Food and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike  
Rockville, MD 20852-1448

Food and Drug Administration  
Center for Devices and Radiological Health  
Program Operations Staff (HFZ-403)  
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 number.*

**FDA-3674 (1/08) (BACK)**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 594-1 - Conical Luer Fittings - General Requirements: 1986

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 6-11

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>		
STANDARD TITLE		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♠ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<b>Paperwork Reduction Act Statement</b>		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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 number.</i></p>		

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 594-2 - Conical Luer Fittings - Lock Fittings: 1998

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 6-129

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>		
STANDARD TITLE		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
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Department of Health and Human Services  
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*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 8536-8 Infusion Equipment for medical use - infusion equipment for use with pressure infusion apparatus

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....  Yes     No  
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes     No  
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....  Yes     No  
 If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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STANDARD TITLE		
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SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009, Biological evaluation of medical devices - Evaluation and Testing

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
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 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation a

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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-7:2008, Biological evaluation of medical devices - ethylene oxide sterilization residuals

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 14-335

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

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 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11135-1:2007, ETO Sterilization

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-331

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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Were there any exclusions from the standard? .....       
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Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971:2007 - Medical Devices - Application of risk management to medical devices

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

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<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<b>Paperwork Reduction Act Statement</b>		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>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 number.</i></p>		

**Section 3: 510k Cover Letter**

This section contains completed FDA 510k Cover Letter

January 16, 2014

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Re: 510(k) Premarket Notification  
TRADITIONAL**

**Infuset™ Flow Control Extension Set**

EMED Technologies Corporation is submitting the enclosed application for Infuset™ Flow Control Extension Sets that are intended to be used with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

We consider our intent to market these devices as confidential commercial information and request that FDA consider it as such.

The submission and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

If you have any questions regarding this 510(k) submission, please contact the undersigned at your earliest convenience.

**Administrative Information**

Proprietary Name: Infuset™ Flow Control Extension Set

Common Name: I.V. Flow Controller

Classification Name and Reference:

Intravascular Administration Set

21 CFR §880.5440

Intended Use: The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

Proposed Regulatory Class: Class II

FDA Panel: General Hospital

Device Product Code: FPA

### Design and Use of the Device

The Infuset™ Flow Control Extension Set consists of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset relies upon the properties inherent to the static fluid path dimensions dictated by the Infuset length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

Table 3-1 below provides additional detail regarding the Infuset™ Flow Control Extension Set.

**Table 3-1**

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X



The power of creative thinking

Thank you for your review of this application.

Regards,

A handwritten signature in blue ink that reads "Peter Kollings".

Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

#### Section 4. Indications for Use Statement

510(k) Number (if known): [TBD]

Device Name: Infuset™ Flow Control Extension Set

Indications for Use: The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use   
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Section 5. 510(k) Summary

**K Number** \_\_\_\_\_

**Submission Date:** January 16, 2014

### General Information

Classification	Class II
Trade Name	Infuset™ Flow Control Extension Set
Common Name:	I.V. Flow Controller
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Submitter	Peter Kollings EMED Technologies Corporation 1264 Hawks Flight Ct., Ste. 200 El Dorado Hills, Ca 95762 Tel: 916.932.0071 x114 Fax: 916.932.0074

### Intended Use

Infuset™ Flow Control Extension Sets are intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

### Predicate Device(s)

Freedom 60 Syringe Infusion Pump System (K933652)

### Device Description

EMED Infuset™ Flow Control Extension Sets are disposable devices allowing users to obtain a controlled and precise rate of fluid flow when used with the RMS Freedom 60 Syringe Infusion Pump System.

Each Infuset™ Flow Control Extension Sets consist of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources

compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset™ Flow Control Extension Sets rely upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

#### **Materials and Characteristics**

Infuset™ Flow Control Extension Sets are equivalent in performance, physical properties, using similar materials, and having the same indications for use as the predicate. Therefore no new issues of safety or effectiveness are introduced by the minimal differences in design.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED Infuset™ Flow Control Extension Sets and the predicate.

**Table 5-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.
Material	PVC	PVC
Design – Lengths	7.5 cm - 97 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

**Performance**

Table 5-2 below summarizes testing results performed to establish conformance of the Infuset™ Flow Control Extension Sets to internal product specifications and requirements, as well as equivalence to the predicate device.

**Table 5-2**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Flow Rate Control (0.9% saline at 20-23°C, with Freedom60)	Range: 202-2244 ml/hr  Precision Less than 5% RSD  Accuracy: +/- 10%	Range: 47 - 1743 ml/hr  Precision Less than 5% RSD  Accuracy: -27% to + 38%
Pressure	Not Less than 25 psi	Not Less than 15 psi

The outcomes of these tests further indicate that the Infuset™ Flow Control Extension Set is substantially equivalent to the predicate accessory in performance, effectiveness, and safety.

### **Biocompatibility**

In accordance with ISO 10993-1:2009 and based on the intended use of the Infuset™ Flow Control Extension Sets, studies were performed including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

**Table 5-3**

<b>Standard</b>	<b>Test Name</b>	<b>Test Result</b>	<b>Other Name</b>
ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
ISO 10993-10	Sensitization	Pass	Kligman Maximization
ISO 10993-10	Irritation	Pass	Intracutaneous Injection
ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
ISO 10993-11	Pyrogenicity	Pass	Rabbit Pyrogen
ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Thromboplastin Time
ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)
USP <85>	LAL Endotoxin Test	Pass	LAL Endotoxin Quantitation Test (Kinetic-QCL Method)

### **Sterility, Shelf-life, and Packaging**

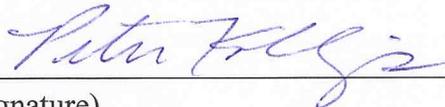
The Infuset™ Flow Control Extension Sets will be sterilized to a sterility assurance level (SAL) of  $10^{-6}$  and with a shelf life of 5 years.

### **Summary of Substantial Equivalence**

EMED Technologies Corporation Infuset™ Flow Control Extension Sets are substantially equivalent to the commercially available predicate device accessory in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Differences between the EMED Infuset™ Flow Control Extension Sets and the predicate do not raise any new issues of safety or effectiveness.

**Section 6. Premarket Notification Truthful and Accurate Statement**  
**[As Required by 21 CFR §807.87(k)]**

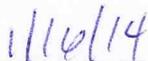
I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance of EMED Technologies Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



\_\_\_\_\_  
(Signature)

Peter Kollings

(Typed Name)



\_\_\_\_\_  
(Date)

\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

\*For a new submission, leave the 510(k) number blank.  
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

**Section 7: Class III Summary and Certifications**

The EMED Infuset™ Flow Control Extension Set is a Class II device and therefore this section is not applicable.

**Section 8: Financial Certification or Disclosure Statement**

There is no clinical data supplied with this notification therefore this section is not applicable.

**Section 9. Declaration of Conformity and Summary Reports**

**As required by 21 CFR §807.87(g)**

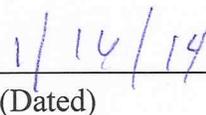
I certify that, in my capacity as Director of Regulatory Affairs and Quality Assurance of EMED Technologies Corporation, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. The EMED Technologies Corporation 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.



\_\_\_\_\_  
(Signature)

Peter Kollings

\_\_\_\_\_  
(Printed Name)



\_\_\_\_\_  
(Dated)

**Section 10: Executive Summary**

EMED Infuset™ Flow Control Extension Sets are disposable devices allowing users to obtain a controlled and precise rate of fluid flow when used with the RMS Freedom 60 Syringe Infusion Pump System.

Infuset™ Flow Control Extension Sets consist of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors.

Each Infuset™ Flow Control Extension Set relies upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

The Infuset™ Flow Control Extension Sets are provided sterile for single use. Each Infuset™ Flow Control Extension Set is sterilized to a sterility assurance level (SAL) of 10<sup>-6</sup> and assigned a shelf life of 5 years.

Table 10-1 below provides a comparison of technological and other characteristics of the Infuset™ Flow Control Extension Set and the predicate.

**Table 10-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Material	PVC	PVC
Design – Lengths	7.5 cm - 97 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

See Section 12 for further information regarding substantial equivalence.

Table 10-2 below summarizes testing results performed to establish conformance of the Infuset™ Flow Control Extension Sets to internal product specifications and requirements, as well as equivalence to the predicate device.

**Table 10-2**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Flow Rate Control (0.9% saline at 20-23°C, with Freedom60)	Range: 202-2244 ml/hr  Precision Less than 5% RSD  Accuracy: +/- 10%	Range: 47 - 1743 ml/hr  Precision Less than 5% RSD  Accuracy: -27% to + 38%
Pressure	Not Less than 25 psi	Not Less than 15 psi

The data and information presented in this pre-market notification will demonstrate that EMED Infuset™ Flow Control Extension Sets are substantially equivalent to the predicate in terms of function, safety, performance, intended use, technology/principles and mechanical properties.

## **Section 11: Device Description**

### **General**

The Infuset™ Flow Control Extension Set consists of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. (b)(4) is used as an adhesive to attach components of the set, but is not used on internal channels or surfaces of Infuset™ Flow Control Extension Sets. Robust componentry and bonding techniques allow Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi.

These sets can be physically connected to fluid sources compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

Infuset™ Flow Control Extension Sets rely upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

### **Design**

Infuset™ Flow Control Extension Sets are assembled from rigid PVC standard luer lock components and specified lengths of medium-density PVC. These sets include slide-clamps used to pinch the tubing and stop the flow of fluid. These fixed-rate flow sets are essentially identical to the predicate in appearance, design, and functionality, and are individually sterile packaged. (b)(4) is used as an adhesive to attach components of the set.

The length and diameter of the tubing results in pre-determined flow rates when the contents of the 60ml syringe are pressurized by the Freedom 60 pump. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. There are no moving pieces or mechanics of these sets designed to alter flow rates.

These sets can be physically connected to the 60ml syringe and patient administrations sets using the standard luer lock connectors, and are provided sterile for single use.

**Materials**

Each Infuset™ Flow Control Extension Set is comprised of the components listed in Table 11-1 below, with detailed specifications and drawing found in Appendix F. The assembly of Infuset™ Flow Control Extension Sets uses only the bonding agent listed in Table 11-1. Plasticizers, lubricants, bonding agents, or other materials used in the manufacture of Infuset™ Flow Control Extension Set components are listed in Table 11-1 with MSDS provided in Appendix F as well.

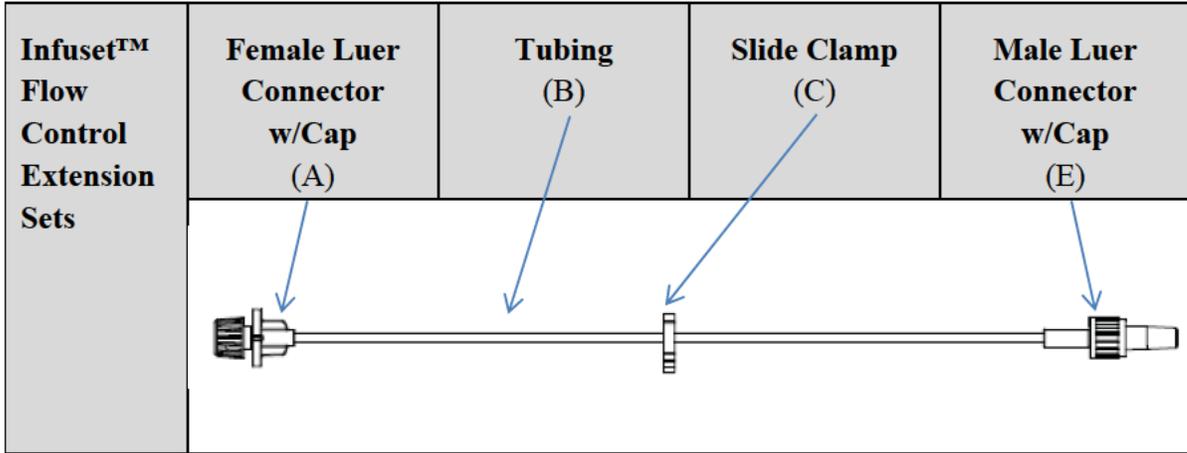
**Table 11-1**

Description	QTY	Units	Material(s)	Additives
(b)(4)				

The fluid path contacting components of the luer locks and tubing are not manufactured with DEHP or natural latex rubber. See Appendix 26 for supporting declarations (b)(4)

Drawing 11-2 below represents the finished Infuset™ Flow Control Extension Set with references to the parts in the table above.

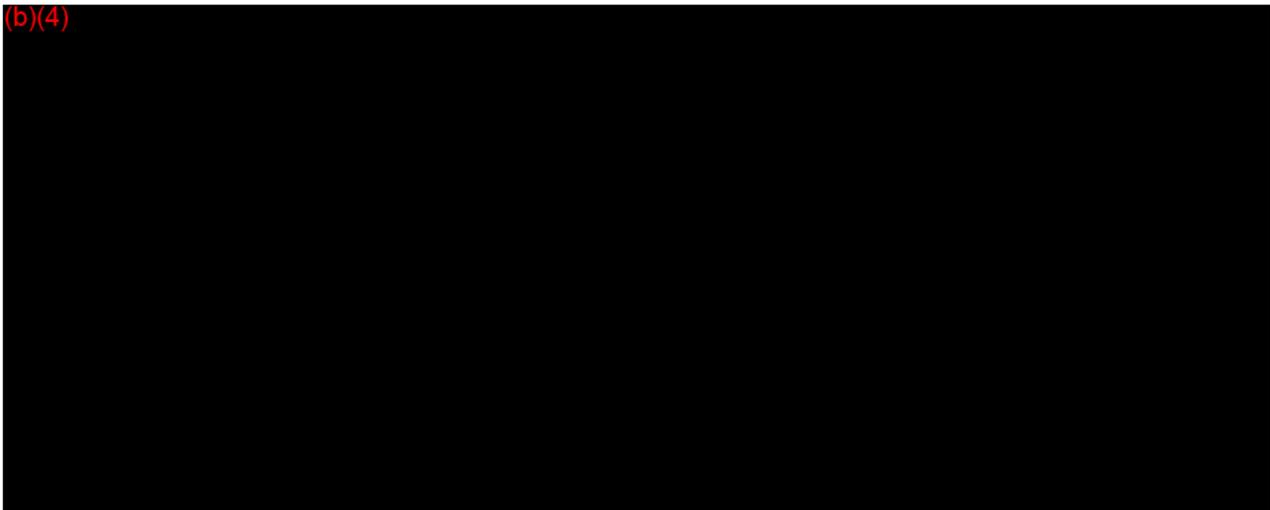
**Drawing 11-2**



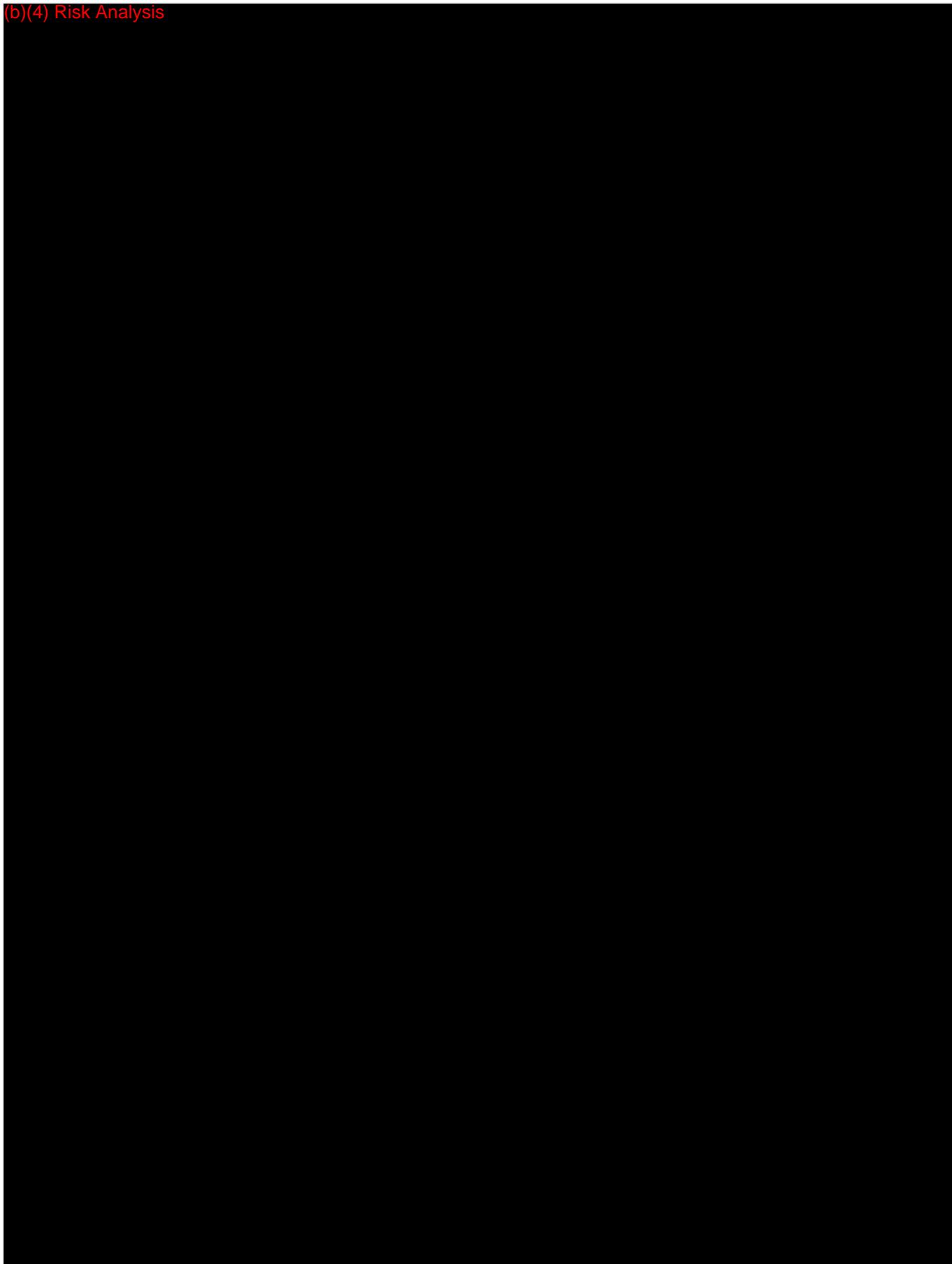
### Method of Operation

Infuset™ Flow Control Extension Sets can be physically connected to fluid sources and/or patient administrations sets using the standard luer lock connectors, and are provided sterile for single use. See the Instructions for Use, Appendix A for information on methods of operation.

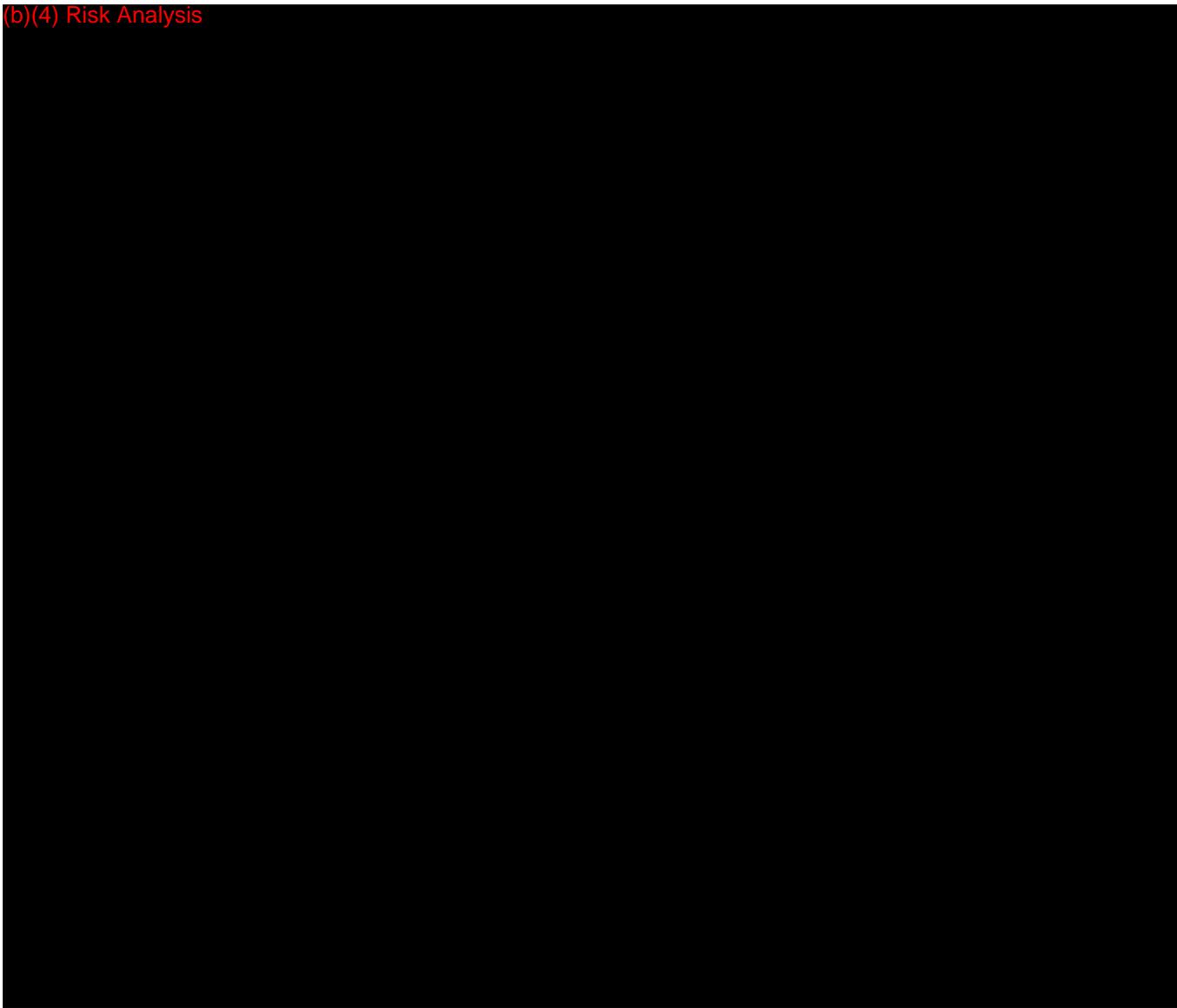
### Risk Analysis



(b)(4) Risk Analysis



(b)(4) Risk Analysis



## Section 12: Substantial Equivalence Discussion

### Predicate Device Comparison

The following section compares the characteristics of EMED Infuset™ Flow Control Extension Sets to the RMS Precision Flow Rate Tubing Set predicates. A presentation of this information is provided immediately below, with a discussion of relevant points and conclusion following. Table 12-1 below provides a comparison of technological and other characteristics of the Infuset™ Flow Control Extension Sets and the predicate.

**Table 12-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Infusion Tubing Set (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.
Material	PVC	PVC
Design – Lengths	7.5 cm - 97 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

## **Discussion**

### Indications for Use Statement

The indications for use of the Infuset™ Flow Control Extension Sets and the predicate are essentially identical

### Materials

The materials that compose each Infuset™ Flow Control Extension Set were identified for their durability, performance, and biocompatibility characteristics. The PVC tubing selected is widely used for medical device applications, and is equivalent to that of the predicate. The materials used in the Infuset™ Flow Control Extension Sets are the same as those used in the predicate.

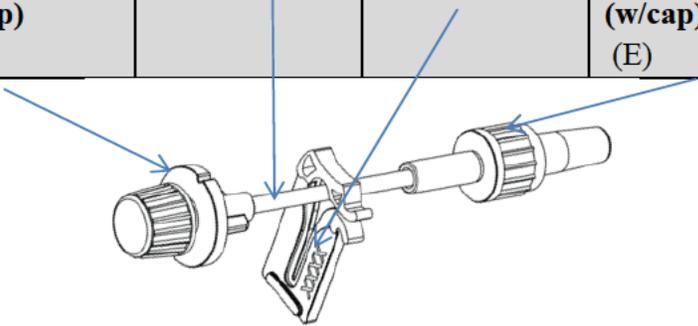
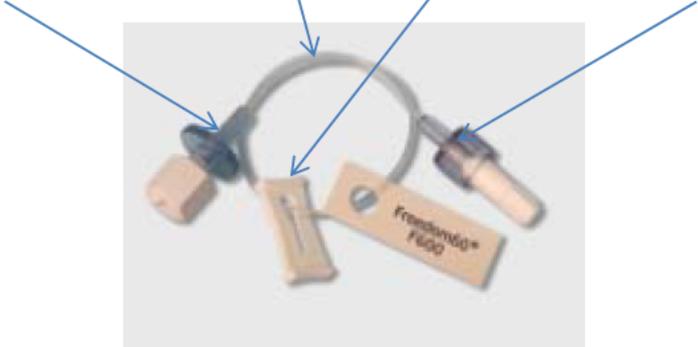
Biocompatibility of the Infuset™ Flow Control Extension Sets conform to ISO 10993 based on intended applications (see Section 15 and Appendix D) and material safety data is available for the Infuset™ Flow Control Extension Set components (see Appendix F).

### Design

The size and weight of the Infuset™ Flow Control Extension Sets and predicate are comparable. Infuset™ Flow Control Extension Sets are intended to be manufactured in several configurations to achieve flow control targets. The lengths of these configurations range from 7.5 cm to 97 cm. The predicates range in length from 34.3 – 100 cm, depending on the configuration and intended flow rate. Residual volumes of the two devices are similar and differences are can be attributed to differences in inner fluid path dimensions.

Table 12-2 below graphically identifies equivalent components in each Infuset™ Flow Control Extension Set and RMS Flow Rate Tubing Set. Following the table is a description of each including physical design, functional operation, and interface requirements.

**Table 12-2**

<b>Infuset™ Flow Control Extension Sets</b>	<b>Female Luer Connector (w/cap) (A)</b>	<b>Tubing (B)</b>	<b>Slide Clamp (C)</b>	<b>Male Luer Connector (w/cap) (E)</b>
				
<b>RMS Precision Flow Rate Tubing Set (K933652)</b>	<b>Female Luer Connector (w/cap) (A)</b>	<b>Tubing (B)</b>	<b>Slide Clamp (C)</b>	<b>Male Luer Connector (w/cap) (E)</b>
				

(A) and (E) Connectors – Both devices use standard luer lock connectors to connect the device to upstream fluid sources and downstream extension and/or patient sets. Infuset™ Flow Control Extension Set luer connectors comply with ISO 594 standards, and therefore ensure compatibility with other infusion sets used throughout industry, as well as the the BD Luer-Lok 60ml (reference #309653) syringe and the Sherwood Medical Monoject 60 ml (reference #8881-560125) syringe required for Freedom 60 use.

Related testing and validation activities are provided in Appendix D.

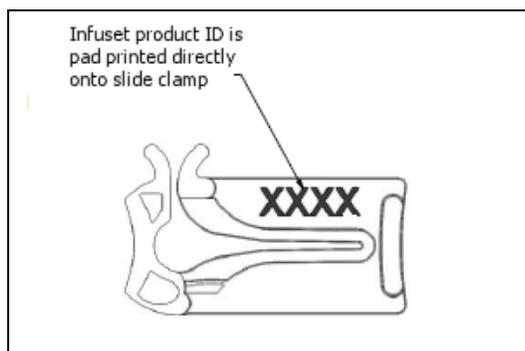
(B) Tubing – The purpose of the tubing is to provide a route for infusion fluid to flow between components of the device. Tubing length for configurations of Infuset™ Flow Control Extension Sets and the predicate flow rate accessory vary to meet target flow rates. The tubing of both the sets is bonded to the luer

locks connectors to assure leakage and strength requirements are achieved, per ISO 8536-8.

Related testing and validation activities are provided in Appendix D.

(C) Slide Clamp – The Infuset™ Flow Control Extension Sets are designed with a slide clamp to stop flow, as does the predicate. The predicate relies upon a separate label to indicate the product code, whereas the Infuset™ Flow Control Extension Set product code is printed directly onto the slide clamp, as demonstrated in Diagram 12-1 below:

**Diagram 12-1**



Any differences in design between the Infuset™ Flow Control Extension Sets and the predicate are not significant in relation to the intended uses of the devices, and do not impact safety, efficacy, or usability of the Infuset™ Flow Control Extension Sets.

### Principle of Action

Both the Infuset™ Flow Control Extension Sets and the predicate flow rate controllers rely on the length and cross-sectional area of the fluid path to control the flow rate. Both devices rely upon the flow controlling properties inherent to the static fluid path dimensions dictated by the tubing length and inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid.

The principle by which both devices achieve flow control is identical in that both rely upon physical dimensions of their fluid paths to control the flow of fluid.

The net flow rate of the liquid through Infuset™ Flow Control Extension Sets and the predicates in real-world situations is derived from the force applied to the liquid, environmental factors, patient's physiological conditions, and viscosity of the fluid.

General Performance

Bench tests were performed using 0.9% saline solution to determine flow rate performance of Infuset™ Flow Control Extension Sets when used with the Freedom 60 Infusion Pump.

From this data target flow rate specifications were selected to ensure that Infuset™ Flow Control Extension Sets provide performance within 10% of stated target values. Table 12-3 below provides a summary of specified flow rates for select Infuset™ Flow Control Extension Set configurations determined through performance testing, accuracy specifications, and difference.

**Table 12-3**

Infuset	Specified Flow Rate (ml/hr)	Accuracy	%RSD
Infuset-190	(b)(4)		
Infuset-290			
Infuset-430			
Infuset-650			
Infuset-820			
Infuset-930			
Infuset-1850			

Testing also compared flow rate controlling abilities of the Infuset™ Flow Control Extension Sets to the RMS Precision Flow Rate Tubing Sets to establish that Infuset™ Flow Control Extension Sets provide flow rate control in line with that of the RMS Precision Flow Rate Tubing Set predicate configurations.

Table 12-4 below provides a summary of test results for RMS Precision Flow Rate Tubing Sets when used with the Freedom 60 infusion pump and 0.9% saline solution.

**Table 12-4**

RMS Set	Target Flow Rate (ml/hr)	Average Flow Rate (ml/hr)	Accuracy	%RSD
F45	(b)(4)			
F60				
F275				
F600				
F900				
F1200				
F2400				

Test results for each target rate are highly concentrated around the mean, as demonstrated by the low relative standard deviation (%RSD). This indicates a high level of precision for these devices – an equivalent level of precision as seen with the Infuset™ Flow Control Extension Sets. The varying magnitudes of difference between test data averages and nominal target values are noted; however, the reason is not known why published RMS Precision Tissue Set target values do not consistently align with empirical results.

It can be seen that the two devices both provide comparable flow rate control with equivalent high levels of precision, and therefore can be considered substantially equivalent in providing flow control to the Freedom 60 infusion system.

It is understood that flow rates can be affected by ambient temperature and patient conditions. The above flow rates were determined at controlled room temperature (20°C - 23°C) without any patient sets or additional tubing downstream of the Infuset™ Flow Control Extension Sets, and are intended to be used as starting points to determine the flow rate for individual patient, as determined by a healthcare professional.

Testing also concluded that the design of the Infuset™ Flow Control Extension Sets effectively interface with the Freedom 60 pump and compatible syringe in the same manner as the predicate RMS Precision Flow Rate Tubing Sets.

Additional studies were performed that verify the ability of the Infuset™ Flow Control Extension Sets to withstand pressures up to 25 psi. This level of pressure resistance is in compliance with ISO 8536-8, *Infusion equipment for medical use - Infusion equipment for use with pressure infusion apparatus*, and exceeds the claimed pressure of 15 psi provided by the Freedom 60 to provide a wide margin of safety.

The results of bench tests demonstrate the substantial equivalence of performance of the Infuset™ Flow Control Extension Sets to that of the predicate when used as indicated. Testing procedures and reports and record of other validation activities are provided in Appendix D.

## Sterilization

Infuset™ Flow Control Extension Sets are ETO sterilized to a sterility assurance level (SAL) of  $10^{-6}$  in accordance with ISO 11135-1 standard, whereas the predicate flow rate controller set achieves necessary sterility levels via radiation.

See Appendix C for additional information regarding the validated ETO sterilization process for Infuset™ Flow Control Extension Sets.

## **Conclusion**

The information presented above, derived from Infuset™ Flow Control Extension Sets material and finished product specifications, validation testing of various Infuset configurations and its components demonstrate that Infuset™ Flow Control Extension Sets are essentially equivalent in function, safety, performance, intended use, technology/principles and mechanical properties to the predicate.

Identified differences between the Infuset™ Flow Control Extension Sets and the predicate have been sufficiently evaluated and risks mitigated. Therefore, Infuset™ Flow Control Extension Sets do not raise any new issues of safety or effectiveness when compared to the predicate, and can be considered essentially equivalent.

**Section 13: Proposed Labeling**

The Instructions for Use, Product Labeling, and other proposed labeling is contained in Appendix A.

**Section 14. Sterilization, Packaging and Expiration Dating**

**Sterilization**

Infuset™ Flow Control Extensions Sets will be sterilized to a sterility assurance level (SAL) of 10<sup>-6</sup> and this process is in compliance with ISO 11355 requirements. Validation of the overkill approach to ETO sterilization (see ISO 1113-1, Annex B) is contained in Appendix C.

Table 14-1 below provides the daily exposure in mg for ETO, ethylene chlorohydrin (ECH), and ethylene glycol (EG) remaining from sterilization of the Infuset™ Flow Control Extensions Sets. It can be seen that these values are well below the thresholds indicated in ISO 10993-7 for prolonged exposure devices, therefore assuring that the sterilization of Infuset™ Flow Control Extensions Sets meets the criteria stipulated in ISO 10993-7 and use of Infuset™ Flow Control Extensions Sets as intended poses minimal risk to the patient.

**Table 14-1**

AERATION TIME (hrs)	Ethylene Oxide (EO) mg/d	Ethylene Chloride (ECH) mg/d	Ethylene Glycol (EG) mg/d
(b)(4)			

This product will be marketed as a pyrogen-free medical device, as supported by pyrogenicity testing (rabbit pyrogen) results provided in Appendix D and discussed in Section 15.

**Packaging and Expiration Dating:**

Infuset™ Flow Control Extension Sets will be supplied in a sterilized package (sealed Dupont Tyvek pouch) with a shelf life of 5 years. This shelf-life is supported by examination and bench testing of (b)(4) samples aged at 55°C equivalent to 5 years real-time storage at room temperature based on Q10 theory within ASTM F1980-07 (2011).

This examination and testing determined that the equivalent of 5 years of storage resulted in no evidence of sterile barrier, product, material, or packaging degradation or discoloration. Study details, data, and shelf-life establishment is documented in Infuset-190 Accelerated Aging testing T(5yr): Product Performance Test to support 5 yrs shelf-life (see Appendix G).

EMED commits to performance testing of products stored at room temperature to support and validate the shelf life derived from accelerated aging testing.

## Section 15: Biocompatibility

### Summary

Individual biocompatibility tests were identified based on the intended use of the Infuset as an extension set that would be used in the administration of intravenous solutions, specifically transferring fluids from a fluid source to a another administrative set. In accordance with ISO 10993-1:2009, the Infuset™ Flow Control Extension Sets were determined to be external communicating devices, with indirect blood path contact for prolonged exposure duration.

Based on this categorization, the following studies were performed by (b)(4) per ISO 10993:2009, ASTM 756, and USP <85> to assess the biocompatibility of the finished EMED Infuset™ Flow Control Extension Sets when used as intended: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility.

All testing met requirements and/or passed the acceptance criteria for biocompatibility set forth in the applicable testing standards.

### Device Description, Components, and Materials

Infuset™ Flow Control Extension Sets are assembled from rigid PVC standard luer lock components and specified lengths of medium-density PVC. These sets include slide-clamps used to pinch the tubing and stop the flow of fluid. Infuset™ Flow Control Extension Sets come in various configurations and lengths. Infuset™ Flow Control Extension Set components and materials are summarized in Table 15-1 below.

**Table 15-1:**

Description	QTY	Material(s)
(b)(4)		

\* Not included in surface area calculation or extraction procedure as these do not make contact with infused liquid during Infuset™ Flow Control Extension Set use.

The materials used in Infuset™ Flow Control Extension Sets are standard in industry for intravenous administrative sets, have well established safety profiles (they are used in other EMED products for several decades), and therefore it was determined that they do not likely pose significant risk to users. Biocompatibility tests were then performed to confirm these conclusions.

#### Evaluation Considerations

Infuset™ Flow Control Extension Sets are designed to be used in connection with other products. Based on the design and intended use of the Infuset™ Flow Control Extension Sets, the following ISO 10993 category was deemed most appropriate external communicating device, with indirect blood path contact between 24 hours and 30 days in duration (i.e. prolonged exposure).

In accordance with ISO 10993-1:2009 and the intended use of Infuset™ Flow Control Extension Sets, the following studies were performed to establish biocompatibility of the finished devices:

- cytotoxicity
- Sensitization
- Irritation
- acute systemic toxicity
- pyrogenicity and endotoxins
- hemocompatibility

#### Sample Preparation and Extraction Conditions

Infuset™ Flow Control Extension Sets samples manufactured under commercial conditions (FP-0010007, Lot 1206072 and Lot 1301089) were provided to the testing lab and extractions were performed per standard (b)(4) procedure. For the majority of the testing, this (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

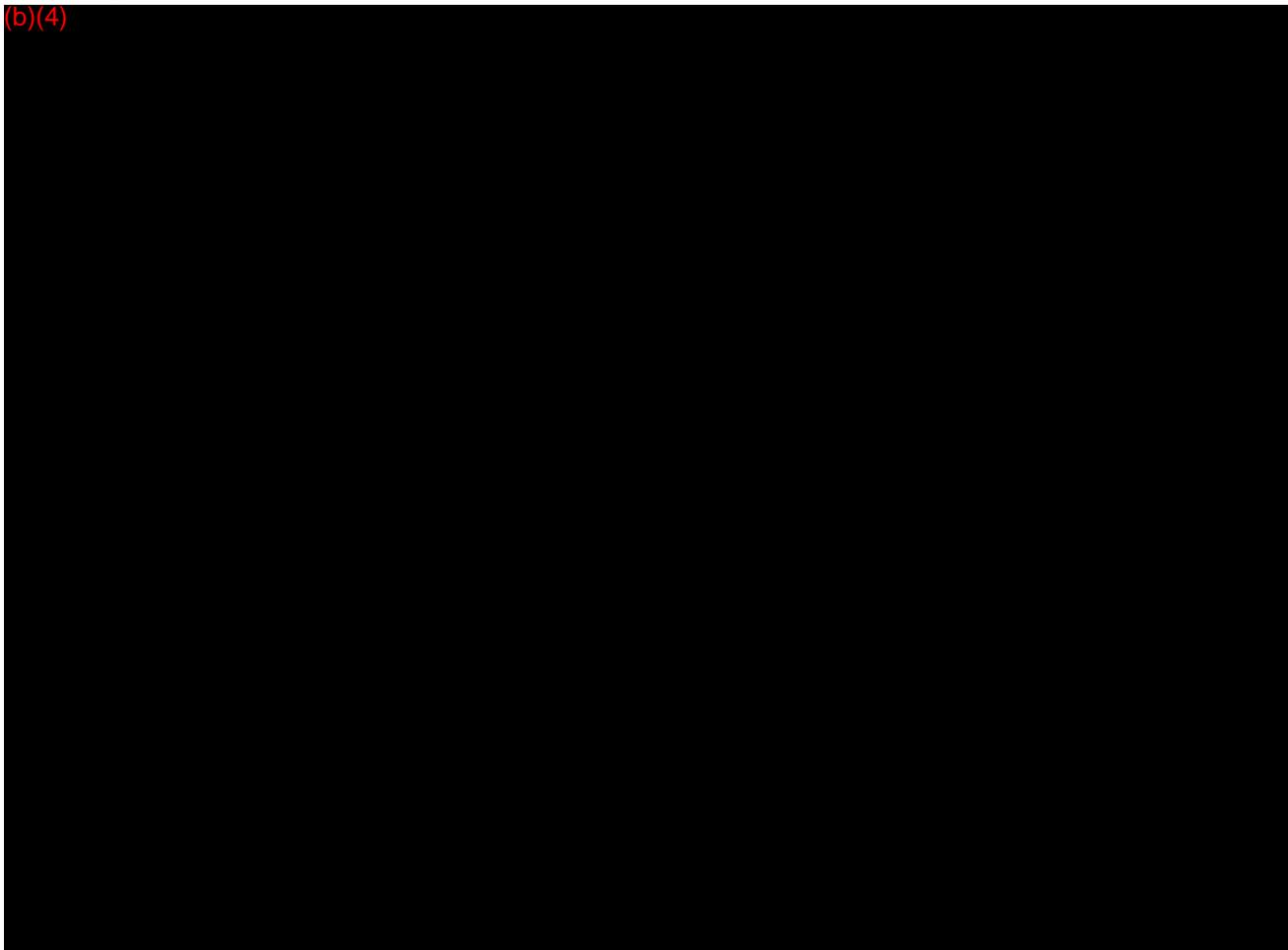
Additional detail regarding sample preparation and extraction for each test is provided in the (b)(4) Final Report found in Appendix G.

EMED (b)(4)

(b)(4)

Total surface area calculations were performed by EMED (b)(4) (b)(4) for determination of the ratio of sample to extraction fluid. Calculations and images are presented in Figure 15-1 below.

**Figure 15-1:**



Testing Results

Biocompatibility test results indicate that the finished devices conform to ISO 10993-1:2009 and ASTM 756. Additionally, the LAL endotoxins test results fall under the limit established in USP <161> for transfusion and infusion assemblies (0.5 EU/mL or 20 EU/device). Therefore, Infuset™ Flow Control Extension Sets can be considered biocompatible and non-pyrogenic.

Tests and test results are summarized in Table 15-2 below.

**Table 15-2: Summary of Testing Performed**

Standard	Test Name	Other Name	Test Result	Report Reference
ISO 10993-5	Cytotoxicity	Neutral Red Uptake	Pass	(b)(4)
ISO 10993-10	Sensitization	Kligman Maximization	Pass	(b)(4)
ISO 10993-10	Irritation	Intracutaneous Injection	Pass	(b)(4)
ISO 10993-11	Acute systemic toxicity	Systemic Injection	Pass	(b)(4)
ISO 10993-11	Pyrogenicity	Rabbit Pyrogen	Pass	(b)(4)
ISO 10993-4	Hemocompatibility	Unactivated Partial Thromboplastin Time	Pass	(b)(4)
ASTM 756	Hemocompatibility	Hemolysis (complete)	Pass	(b)(4)
USP <85>	Endotoxins	Limulus amoebocyte lysate (LAL) Endotoxin	Pass	(b)(4)

**Conclusion**

All testing of Infuset™ Flow Control Extension Sets met requirements and/or passed the acceptance criteria for biocompatibility set forth in the applicable testing standards for a surface device, with mucosal membrane contact less than or equal to 24 hours in duration. Therefore, Infuset™ Flow Control Extension Set can be considered conforming to ISO 10993:2009, Biological Evaluation for Medical devices requirements for their intended use.

Biocompatibility test protocols, results, and reports are provided in Appendix G.

**Section 16: Software**

The EMED Infuset™ Flow Control Extension Set does not include software and therefore this section is not applicable.

**Section 17: Electromagnetic Compatibility and Electrical Safety**

The EMED Infuset™ Flow Control Extension Set does not include any electrical components or elements and therefore this section is not applicable.

**Section 18: Performance Testing – Bench**

Various performance tests were performed to verify Infuset™ Flow Control Extension Sets successfully satisfied user and product requirements, and to establish substantial equivalency between Infuset™ Flow Control Extension Sets and the predicate. Table 18-1 below contains a summary of the critical bench top performance tests performed and the conclusions drawn from those tests. Supplemental testing performed during the design and development of Infuset™ Flow Control Extension Sets has been captured in the product Design History File per 21.CFR.820 and internal Design Control requirements.

Additional detail regarding method, apparatus, performance, and acceptance criteria of the below tests is captured in test protocols and reports are provided in Appendix D.

**Table 18-1**

Title	Purpose	Results	Conclusions
<p>(b)(4) [Redacted] Infuset Design Verification Report</p>	<p>To qualify product performance, based on maintaining the specified design requirements for the Infuset device.</p> <p>To establish that design characteristics meet ISO 8536-4 and 8536-8 requirements.</p> <p>Characteristics tested include leakage (at 30 psi), occlusion, bonding force strength, and priming volume.</p>	<p>No failure was observed for any of the tested characteristics.</p>	<p>All tests have been performed completely and all acceptance criteria have been proved to be met. The design can be considered verified.</p>

Title	Purpose	Results	Conclusions
(b)(4) 2 Male Luer Lock Verification	To qualify product performance for the male luer lock connector (b)(4) in general requirements and lock fittings.	All test results of the male luer lock connector (b)(4) met requirements.	This component can be considered compliant with product specifications and ISO 594-1/594-2 standards.
FLL (b)(4) (b)(4) Validation Report	To qualify product performance for the female luer lock connector (b)(4) in general requirements and lock fittings.	All test results of the female luer lock connector (b)(4) met requirements.	This component can be considered compliant with product specifications and ISO 594-1/594-2 standards.
(b)(4) Infuset-190 Accelerated Aging Testing T(5yr)	To demonstrate that the sterile barrier of the Infuset product is maintained and that the device continues to meet specifications after accelerated aging equivalent to 5 years of real-time storage to support shelf-life claims.	Visual examination indicated no evidence of product/material degradation, discoloration, or label legibility. Sterile barrier remained intact.	Testing results indicate the sterile barrier of the Infuset pouch is maintained during accelerated aging equivalent to 5 years of real-time storage, and that the product materials

Title	Purpose	Results	Conclusions
<p>(b)(4) Flow rate testing with Freedom60 Pump - Flow Rate Testing with 0.9% saline solution</p>	<p>To establish safe and effective use of the Infuset when used with the Freedom 60 pump.</p> <p>Also to validate target flow rate values and tolerances of Infusets when used with the Freedom 60 pump, and compare performance of RMS Precision Tissue Infusion Sets.</p>	<p>No evidence of leakage from luer connectors, tubing joints, or from flow regulator component.</p> <p>All luer connectors successfully interfaced with IV tubing.</p> <p>Flow rate data acquired for various Infusets and RMS sets.</p>	<p>The Infuset extension sets successfully and safely interfaced with the Freedom 60 pump and 60 ml BD Syringe.</p> <p>Target flow rate values and tolerances were established.</p> <p>Infusets deliver satisfactory performance comparable to that of the RMS sets.</p>

**Section 19: Performance Testing – Animal**

No animal testing was performed in support of this notification.

**Section 20: Performance Testing – Clinical**

No clinical testing was performed in support of this notification.

## **Appendix A: Instructions for Use and Labeling**

This appendix contains the following:

<b>Exhibit</b>	<b>ID</b>	<b>Description</b>
1	AS-0010037	Artwork, Infuset-190 (representative example)
2	AS-0010041	Infuset IFU
3	AS-0010067	Artwork Infusion Box
4	AS-0010038	Artwork Inner Box Label, Infuset-190 (representative example)

3.750 in



# Infuset-190

Reorder No. / REF **FP-0010008**

Infusion extension set (en) Dispositif de perfusion (fr)  
 Equipo de infusión (es) Infusionset (de)  
 Set di infusione (it) инфузионный набор (ru)  
 Infusionsset (sv) Infusionsetti (fi)  
 Infusionsæt (da) Infusionssett (no)

← 51.76cm, ø0.3mm ID, ø2.4mm OD  ≈ **0.14ml**   
 Approximate priming volume.

QTY: <b>1 ea.</b> LOT XXXXXXXX	Manufacture Date: DD.MMM.YEAR Expiration Date: DD.MMM.YEAR
CAUTION. Consult the instructions for use.	Do not use if package is damage.
<b>STERILE EO</b>	Do not re-use. <b>Non-Pyrogenic</b>
<b>DEHP NO</b> This product is not made with di(2-ethylhexyl) phthalate.	40°C -5°C Storage temperature limits.
<b>Latex NO</b> This product is not made with natural rubber latex.	
<b>RxOnly</b> CE 0459	

**CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

**EC REP** European Representative:  
**Meridian Medical Ltd.**  
 Unit 1, Thorogate Road  
 Lineside Industrial Estate  
 Littlehampton, West Sussex BN17 7LU  
 Telephone: +44 (0) 1903 732 344  
 Fax: +44 (0) 1903 732 348  
 Email: admin@meridian-medical.com

**Manufactured for:**  
**EMED Technologies Corporation.**  
**Assembled in Mexico from US components.**  
 1264 Hawks Flight Ct, Suite 200  
 El Dorado Hills, CA 95762 USA  
 Telephone: +(1) 916.932.0071  
 Fax: +(1) 916.932.0074  
 Email: info@emedtc.com  
 Website: www.emedtc.com



AS-0010037\_3.0-A

REVISION HISTORY			
REV	DCR#	CHANGE DESC.	DATE
1.0	12122011-01	INITIAL RELEASE	12/14/11
1.1	04182012-02	Updated REF# and Symbols	04/18/12
1.2	05182012-01	Changed MFG by to for: Added Assy in Mex.	05/18/12
2.0	10152012-01	Changed notes	11/15/12
3.0-A	12132013-02	Added symbols subtitles	12/13/12

Notes (Unless Otherwise Specified)

1. COLOR: ARTWORK TO BE PRINTED IN BLUE PMS 285.

2. PRINT ARTWORK ON TYVEK SIDE OF POUCH.

3. POUCH SIZE: 3.75" X 8.00"

4. PRINT MANUFACTURE AND EXPIRATION DATE AND LOT NUMBER PER EMED'S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

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ENG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/13
CHECKED.			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/13

EMED Technologies Corporation 1264 Hawks Flight Suite 200 El Dorado Hills CA, 95762 Tel. 916.932.0071 www.emedtc.com	<b>TITLE:</b> <b>Artwork, Pouch, Infuset-190</b>	
	<b>ARTWORK #</b> AS-0010037	<b>REV.</b> 3.0-A
SIZE: A SCALE: 1:1 SHEET: 01 OF 1	TEMPLATE NO: MF-0013 REV 1.2	

## Infuset Flow Control Extension Set

## Instructions for Use

PICTURES	ENGLISH
<p><b>WARNING:</b></p> 	<ul style="list-style-type: none"> <li>• The Infuset™ Flow Control Extension Set is intended for use with the RMS Freedom 60 Syringe Infusion Pump System (K933652) to provide flow rate control to administer fluids from a container to a patient's vascular system.</li> <li>• Single use only; reuse can result in infection, and cross contamination</li> <li>• Do not re-sterilize</li> <li>• Use aseptic technique</li> <li>• Follow pharmacy / physician instructions</li> <li>• <b>U.S. Federal Law restricts this device to sale by or on order of a physician</b></li> </ul>
<p>1</p> 	<p>Wash hands before handling any supplies</p>
<p>2</p>	<p>Remove Infuset from packaging</p>
<p>3</p> 	<p>Load syringe with drug</p>
<p>4</p> 	<p>Connect syringe (MLL) to Infuset (FLL)</p>
<p>5</p>	<p>Connect Infuset (MLL) to patient set (FLL)</p>
<p>6</p> 	<p>Prime set (be careful not to waste fluid) per your pharmacy / physician instructions.</p>
<p>7</p> 	<p>Use provided slide clamp to prevent flow of fluid.</p>
<p>8</p> 	<p>Load syringe onto Freedom 60 Infusion pump. Be sure the tubing luer disc is fully seated in the pump's nose.</p>
<p>9</p>	<p>Operate Freedom 60 Infusion pump per User Manual and pharmacy / physician instructions directions.</p>
<p>10</p> 	<p>Complete the infusion and disconnect Infuset from patient / equipment per your pharmacy / physician instructions</p>
<p>11</p> 	<p>Dispose in appropriate waste container</p>

## Infuset Flow Control Extension Set

### Instructions for Use

	SYMBOLS	ENGLISH
1		Warning
2		Read the instructions
3		Do not re-use
4		Don't use if package is damaged
5	<b>STERILE EO</b>	Sterilized by Ethylene Oxide
6		Manufacturer
7	<b>EC REP</b>	EC Representative
8	<b>REF</b>	Reference number
9		Manufacturing date
10	<b>LOT</b>	Batch
11		Expiration date
12		Quantity
13		Storage temperature limits
14	<b>SN</b>	Serial number
15	$\varnothing$	Diameter
16		Length
17	<b>Rx ONLY</b>	To sale by or on the order of a physician.
18		Approximate priming volume
19	<b>CE</b>	CE Mark
20	<b>ID</b>	Internal Diameter
21	<b>OD</b>	Outer Diameter
22		Non-pyrogenic fluid path

### Infuset Flow Rates

(0.9% saline at 20-23°C, with Freedom60)

EMED Infuset Reorder Number	Description	Expected Flow Rate	Accuracy
FP-0010008	Infuset-190	202 ml/hr	+/- 10%
FP-0010007	Infuset-290	305 ml/hr	+/- 10%
FP-0010010	Infuset-430	444 m/hr	+/- 10%
FP-0010009	Infuset-650	610 ml/hr	+/- 10%
FP-0010006	Infuset-820	817 ml/hr	+/- 10%
FP-0010005	Infuset-930	939 ml/hr	+/- 10%
FP-0010004	Infuset-1850	2244 ml/hr	+/- 10%

**NOTE:** Flow rates can be affected by ambient temperature and patient conditions. The above flow rates were determined at controlled room temperature (20°C - 23°C) without any patient sets or additional tubing downstream of the Infuset, and are intended to be used as starting points to determine the flow rate for individual patient, as determined by a healthcare professional.

APPROVALS:  
ENG: Carlos G. 11/06/12  
S&M:  
QA:

**EMED Technologies Corporation.**

Artwork Infusion box2 (large size)  
P/N AS-0010067 REV 1.0-RD-A

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**IMPORTANT**  
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**FONTS: OUTLINED**  
Fonts are not supplied with this artwork.

**COLO**



REV 1.0-RD-A, INITIAL DRAFT



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Harnessing innovation that makes medical breakthroughs accessible to patients worldwide is our passion and focus.

*Raising the standard in product safety and efficacy.*



- We are a full-line Infusion Therapy healthcare supplier with the following groups of products:**
- Disposable, semi-disposable and reusable Infusion Pumps
  - Infusion Sets
  - Filter Sets
  - Flow Regulator Sets
  - Drug Reconstitution Sets
  - Huber Sets
  - In-line Filter Sets
  - Special Configuration Sets
  - Custom Products
  - Infusion Components

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www.emedtechnologies.com

**EMED Technologies Ltd**  
10000 Woodbine Avenue, Unit 10, Markham, ON L3R 9K7, Canada  
Tel: +1 (416) 932-2074  
Fax: +1 (416) 932-2074  
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**STERILE**  
ISO 13485



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REVISION HISTORY

REV	DCR#	CHANGE DESC.	DATE
1.0	12122011-01	INITIAL RELEASE	12/14/11
1.1	04182012-01	Updated reorder# and added flowrate.	04/18/12
2.0	10152012-01	Updated Desc. & replaced flowrate w/ dim's, Changed box QTY to 25	11/15/12
3.0-A	12132013-02	Added symbols subtitles	12/13/13

Notes (Unless Otherwise Specified)

1. PRINT COLOR BLACK INK
2. PRINT ON 4inX2.5in THERMAL TRANSFER LABEL.
3. USE COREL ARTWORK FILE TO PRINT LABEL PROVIDED BY EMED.
4. PRINT MANUFACTURE DATE AND EXPIRATION DATE FIVE YEARS FROM MFG DATE AND LOT NUMBER PER EMED'S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

**Infuset-190 Reorder No. / REF FP-0010008**

<p>Infusion extension set (en)                  Dispositif de perfusion (fr)                  Equipo de infusión (es)                  Infusionset (de)                  Set di infusione (it)                  инфузионный набор (ru)                  Infusionsset (sv)                  Infusionsetti (fi)                  Infusionssæt (da)                  Infusionssett (no)</p>	<p> QTY: <b>25 ea.</b></p> <p> Manufacture Date: <b>DD.MMM.YEAR</b></p> <p> Expiration Date: <b>DD.MMM.YEAR</b></p> <p><b>LOT XXXXXX</b></p> <p><b>RxOnly</b></p> <p> ≈ <b>0.14ml</b>  Approximate priming volume.</p> <p> ←→ 51.76cm, ø0.3mm ID, ø2.4mm OD</p> <p style="text-align: right; font-size: small;">AS-0010008_3.0-A</p>
--	--

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DRAWN.	Carlos G.	[ON FILE PER DCR]	12/13/13	
ENG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/13	
CHECKED.				TITLE: <b>Artwork, Inner Box Label, Infuset-190</b>
MFG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/13	ARTWORK NO. <b>AS-0010038</b> REV. <b>3.0-A</b>
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118				TEMPLATE NO: MF-0013 REV 1.2

## **Appendix B: Predicate Labeling**

This appendix contains the following:

<b>Exhibit</b>	<b>Description</b>
1	Example RMS Precision Flow Rate Tubing Set
2	RMS flow controller accessory IFU

# FREEDOM60<sup>®</sup>

Syringe Infusion System

REF **F2400**

LOT **1.347/11**

 **2016-12**

CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.



**STERILE R**



**CE** 0297

- Sterile Tubing Set (en)
- Set di tubi sterile (it)
- Steriles Schlauchset (de)
- Conjunto de tubo estéril (es)
- Tubulure sterile (fr)
- Sterilt slangesett (no)
- Steril slanguppsättning (sv)
- Steriili letkustopakkaus (fi)
- Sterilt slangesæt (da)

**EC REP**

RMS UK Ltd,  
28 Trinity Rd,  
Nailsea, Somerset  
BS48 4NU, UK



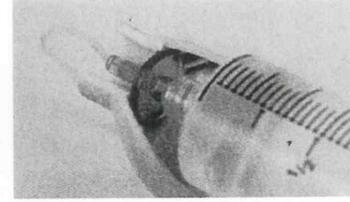
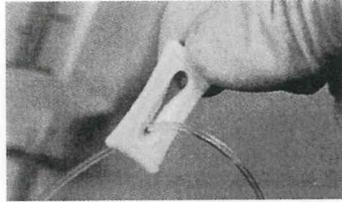
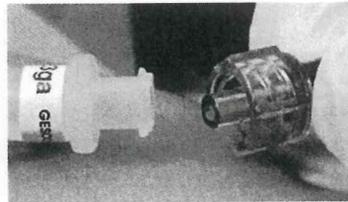
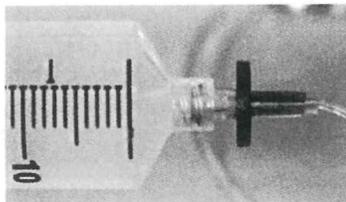
RMS Medical Products  
24 Carpenter Rd.  
Chester, NY 10918 USA  
800-624-9600 toll free  
845-469-2042 local  
[www.rmsmedpro.com](http://www.rmsmedpro.com)

7051



**Freedom60® Sterile Tubing Set**

*Instructions • Istruzioni • Gebrauchsanleitung • Instrucciones • Instructions • Instruksjoner • Instruktioner • Ohjeet • Vejledning*



Connect the luer disc end of the tubing set to the syringe.

Connect the male end of the tubing set to the indwelling catheter (IV) or needle set (Sub-q).

To immediately stop flow in the case of an emergency, pull the tubing through the slide clamp.

When inserting the syringe into the pump, make sure the tubing luer disc is fully seated in the pump's nose.

Collegare alla siringa l'estremità del disco luer del set di tubi.

Collegare l'estremità maschio del set di tubi al catetere a dimora (endovenoso) o al set di aghi (Sub-q).

Per arrestare immediatamente il flusso in caso di emergenza, tirare i tubi attraverso il morsetto scorrevole.

Quando si inserisce la siringa nella pompa, accertarsi che il disco luer dei tubi sia completamente alloggiato nell'estremità anteriore della pompa.

Den Luer-Anschluss des Schlauchsets an die Spritze anschließen.

Den Stecker des Schlauchsets mit dem Verweilkatheter (IV) oder dem Nadelsatz (Sub-Q) verbinden.

Um im Notfall den Fluss sofort stoppen zu können, ziehen Sie den Schlauch durch die Schiebeklemme.

Beim Einführen der Spritze in die Pumpe unbedingt sicherstellen, dass der Luer-Anschluss des Schlauchs vollständig und sicher in der Pumpennase sitzt.

Conecte el extremo del disco luer del conjunto de tubos a la jeringa.

Conecte el extremo macho del conjunto de tubos al catéter permanente del paciente (IV) o al juego de agujas subcutáneas.

Para detener inmediatamente el flujo en caso de una emergencia, tire del tubo a través de la pinza deslizable.

Cuando inserte la jeringa en la bomba, asegúrese de que el disco luer del tubo se queda completamente asentado en la nariz de la bomba.

Connecter l'extrémité du disque Luer de la tubulure sur la seringue.

Connecter l'extrémité mâle de la tubulure au cathéter à demeure (IV) ou à l'aiguille (sous-cutanée).

Pour interrompre immédiatement le débit en cas d'urgence, tirer la tubulure au travers du clamp coulissant.

Lors de l'insertion de la seringue sur la pompe, s'assurer que le disque Luer de la tubulure soit correctement positionné sur le bec de la pompe.

Koble endestykket av luerskiven til rørsettet på sprøyten.

Koble handdelen av rørsettet til det intravenøse kateteret (IV) eller nålsettet (Sub-q).

For å umiddelbart stoppe gjennomstrømning i nødstilfelle, dras slangen gjennom skliklemmen.

Når sprøyten settes inn i pumpen, må det påses at rørets luerskive er godt festet i nesen på pumpen.

Anslut luerskivans ända av slangen till sprutan.

Anslut slangens hanända till den kvarliggande katetern (IV) eller nåluppsättningen (Sub-q).

Om du behöver stoppa flödet vid nödfall, drardu slangen genom glidklämman.

När du för in sprutan i pumpen kontrollerar du att slangens luerskiva sitter helt på plats i pumpens nos.

Liitä letkuston luer-laippapää ruiskuun.

Liitä letkuston koiraspää kestokatetriin (IV) tai neulasarjaan (Sub-q).

Hätätilanteessa virtaus loppuu välittömästi, kun vedät letkun liukupuristimen läpi.

Varmista asettaessasi ruiskua pumppuun, että letkun luer-laippa on sovitettu hyvin pumpun kärkeen.

Monter enden af luerskiven på slangesættet, til sprøjten.

Tilslut han-enden af slangesættet til det fastliggende kateter (IV) eller nålesæt (sub-q).

Gennemstrømningen standses i nødtilfælde ved at trække slangen igennem skydeklemmen.

Når sprøjten indsættes i pumpen, skal det kontrolleres at slangens luerskive sidder korrekt i spidsen af pumpen.



RMS Medical Products • Chester, NY 10918 USA • Ph: 800-624-9600 or 845-469-2042  
RMS UK Ltd, Nailsea, Somerset BS48 4NU, UK



www.freedom60.com

342101

### Appendix C: Sterilization Validation

This appendix contains the following:

Exhibit	ID	Description
1	(b)(4)	[REDACTED] Sterilization Validation Protocol
2	(b)(4)	[REDACTED] Sterilization Validation Report

\*NOTE: Protocol and report attachments, supporting data, and supplemental information are not included due to their large size but are maintained at EMED Technologies as part of the complete TR-007 validation file.

































**Appendix D: Performance Testing**

This appendix contains the following:

Exhibit	ID	Description
1	(b)(4)	(b)(4) Verification Report
2	(b)(4)	(b)(4) Male Luer Lock Validation
3		FLL Mold Validation Report
4		Infuset-190 Accelerated Aging Testing T(5yr)
5		Flow rate testing with Freedom60 Pump - Flow Rate Testing with 0.9% saline solution







































































































































































































**Appendix E: Biocompatibility**

This appendix contains the following information to support biocompatibility claims:

<b>Exhibit</b>	<b>Standard</b>	<b>Test Name</b>	<b>Test Result</b>	<b>Other Name</b>
1	ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
2	ISO 10993-10	Sensitization	Pass	Kligman Maximization
3	ISO 10993-10	Irritation	Pass	Intracutaneous Injection
4	ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
5	ISO 10993-11	Pyrogenicity	Pass	Rabbit Pyrogen
6	ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Thromboplastin Time
7	ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)
8	USP <85>	LAL Endotoxin Test	Pass	LAL Endotoxin Quantitation Test (Kinetic-QCL Method)

























































































































































































































































































**Appendix F: Device and Component Specifications**

This appendix contains the Infuset component and device specifications listed in Table F-1 and the MSDS documents for plasticizers, lubricants, bonding agents, or other materials used in the manufacture of Infuset™ Flow Control Extension Sets or its components are listed in Table F-2.

**Table F-1**

Exhibit	Part No.	Component Description
1	(b)(4)	
2		
3		
4		
5		
6		
7		
8		
9		

**Table F-2**

Exhibit	Material Description	Material Use
10	(b)(4)	
11		
12		
13		
14		

Provided as Exhibit 15 is a formal declaration from the manufacturer of the above luer and tubing components that the components do not contain DEHP and the latex is not used in the manufacturing or handling of these components. Exhibit 16 is an assertion from the (b)(4) that natural latex rubber is not used in those processes.













































































K140133/3001

FDA CDRH DMC  
APR 15 2014  
Received

4/11/14

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G0609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Re: Response to Request for Additional Information – Infuset Flow Control Extension Set (K140133)**

The following is the additional information requested on 3/19/14 to support the pre-market notification for the EMED Technologies Corporation Infuset Flow Control Extension Set (K140133)

The submitted information and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,



Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
EMED Technologies Corporation

Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

4/11/14

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - WO66-G0609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

**Re: Response to Request for Additional Information – Infuset Flow Control Extension Set (K140133)**

The following is the additional information requested on 3/19/14 to support the pre-market notification for the EMED Technologies Corporation Infuset Flow Control Extension Set (K140133)

The submitted information and attachments are provided as one original and eCopy duplicate as required by regulation. The eCopy is an exact duplicate of the paper copy.

Please contact the undersigned at your earliest convenience if there are any questions regarding the responses or information provided.

Regards,

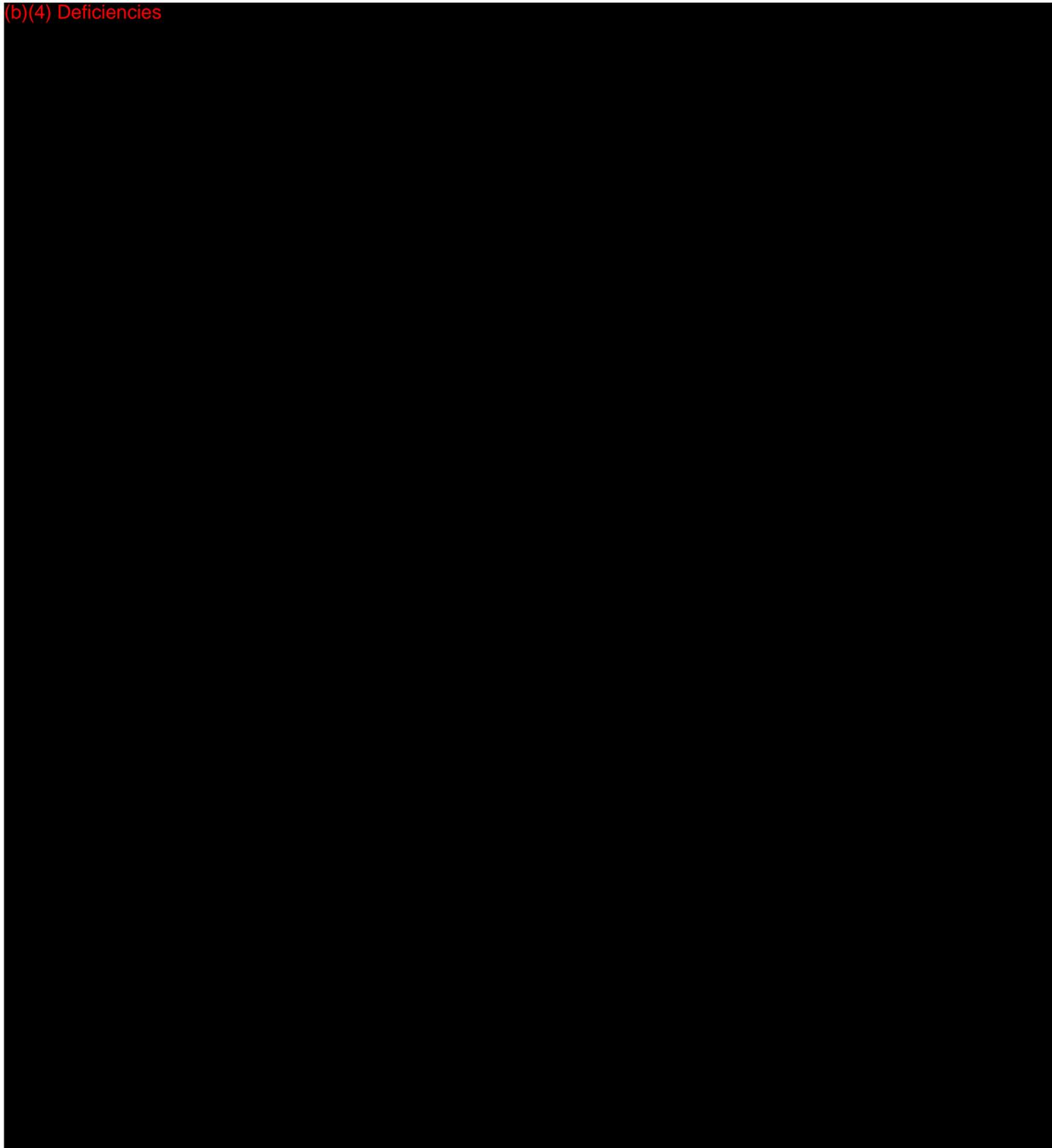


Peter Kollings  
Director Regulatory Affairs and Quality Assurance  
EMED Technologies Corporation

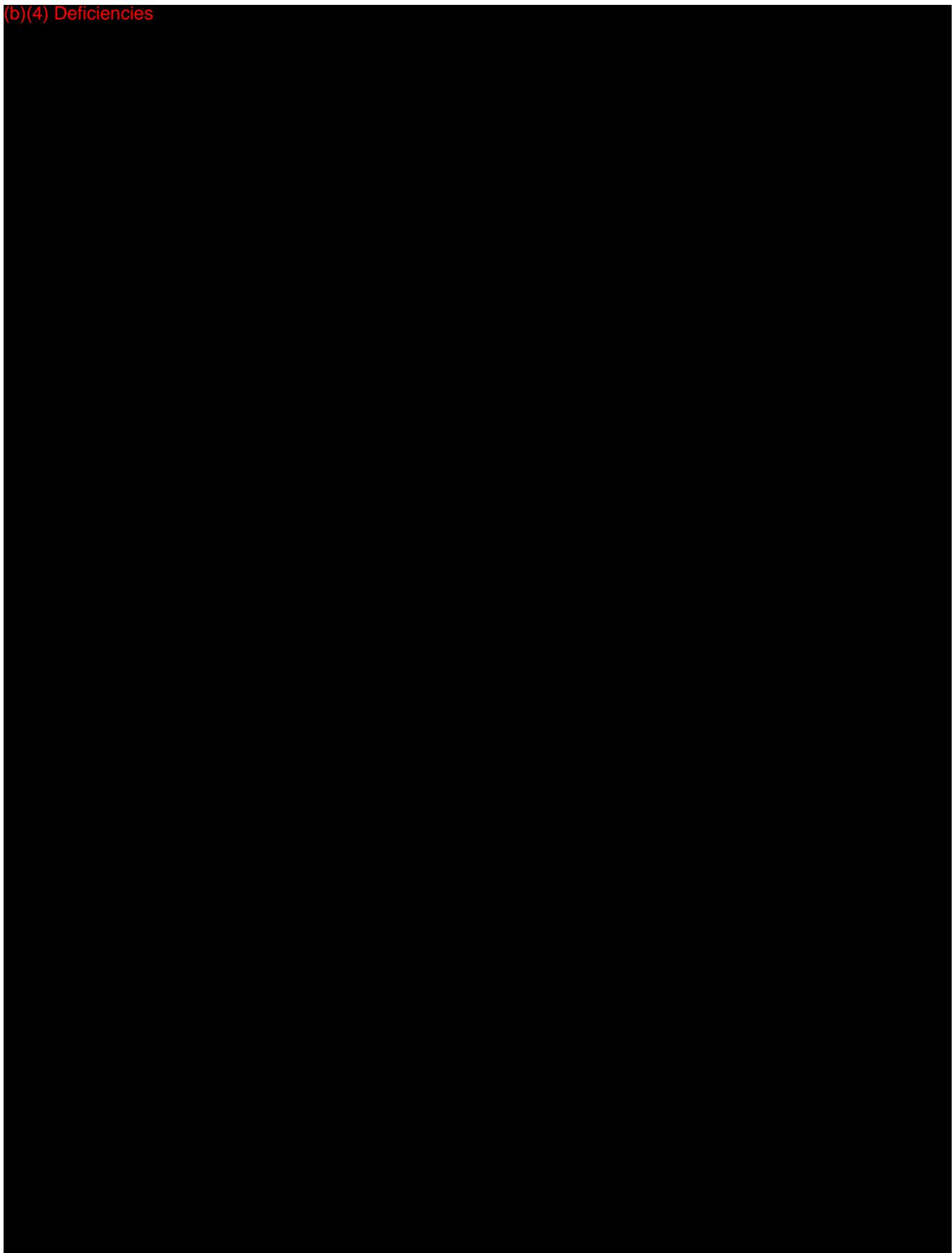
Cc: Paul Lambert, CEO and President, EMED Technologies Corporation

**K140133 Additional Information Request Response (3/11/14)**

(b)(4) Deficiencies



(b)(4) Deficiencies



## **Appendix 1: Updated 510k Sections**

This appendix contains the updated Section 5, 510k Summary and Section 12-1, Substantial Equivalence Discussion.

## Section 5. 510(k) Summary

**K Number** \_\_\_\_\_

**Submission Date:** January 16, 2014

### General Information

Classification	Class II
Trade Name	Infuset™ Flow Control Extension Set
Common Name:	I.V. Flow Controller
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Submitter	Peter Kollings EMED Technologies Corporation 1264 Hawks Flight Ct., Ste. 200 El Dorado Hills, Ca 95762 Tel: 916.932.0071 x114 Fax: 916.932.0074

### Intended Use

Infuset™ Flow Control Extension Sets are intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.

### Predicate Device(s)

Freedom 60 Syringe Infusion Pump System (K933652)

### Device Description

EMED Infuset™ Flow Control Extension Sets are disposable devices allowing users to obtain a controlled and precise rate of fluid flow when used with the RMS Freedom 60 Syringe Infusion Pump System.

Each Infuset™ Flow Control Extension Sets consist of a given length of medium-density PVC tubing and rigid PVC standard luer lock connectors. Robust componentry and bonding techniques allow the Infuset™ Flow Control Extension Sets to withstand fluid pressures up to 25 psi. These sets can be physically connected to fluid sources

compatible with the Freedom60 Syringe Infusion System and patient administrations sets using the standard luer lock connectors. The Infuset™ Flow Control Extension Sets are provided sterile for single use.

The Infuset™ Flow Control Extension Sets rely upon the properties inherent to the static fluid path dimensions dictated by the Infuset™ Flow Control Extension Set length and tubing inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid. Available configurations with differing lengths and tubing diameters offer users several target flow rates to choose from.

This basic construction and principle of action are essentially identical to that of the predicate flow control accessory that has had market clearance and been actively marketed for decades.

**Materials and Characteristics**

Infuset™ Flow Control Extension Sets are equivalent in performance, physical properties, using similar materials, and having the same indications for use as the predicate. Therefore no new issues of safety or effectiveness are introduced by the minimal differences in design.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED Infuset™ Flow Control Extension Sets and the predicate.

**Table 5-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.
Material	PVC	PVC
Design – Lengths	7.5 cm - 59 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

### Performance

Table 5-2 below summarizes testing results performed to establish conformance of the Infuset™ Flow Control Extension Sets to internal product specifications and requirements, as well as equivalence to the predicate device.

**Table 5-2**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Flow Rate Tubing Sets (K933652)</b>
Flow Rate Control (0.9% saline at 20-23°C, with Freedom60)	Range: 202-2244 ml/hr  Precision Less than 5% RSD  Accuracy: +/- 10%	Range: 47 - 1743 ml/hr  Precision Less than 5% RSD  Accuracy: -27% to + 38%
Pressure	Not Less than 25 psi	Not Less than 15 psi

The outcomes of these tests further indicate that the Infuset™ Flow Control Extension Set is substantially equivalent to the predicate accessory in performance, effectiveness, and safety.

### **Biocompatibility**

In accordance with ISO 10993-1:2009 and based on the intended use of the Infuset™ Flow Control Extension Sets, studies were performed including the following: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and hemocompatibility. Table 5-3 presents a summary of testing and results indicating compliance with biocompatibility standards.

**Table 5-3**

<b>Standard</b>	<b>Test Name</b>	<b>Test Result</b>	<b>Other Name</b>
ISO 10993-5	Cytotoxicity	Pass	Neutral Red Uptake
ISO 10993-10	Sensitization	Pass	Kligman Maximization
ISO 10993-10	Irritation	Pass	Intracutaneous Injection
ISO 10993-11	Acute systemic toxicity	Pass	Systemic Injection
ISO 10993-11	Pyrogenicity	Pass	Rabbit Pyrogen
ISO 10993-4	Hemocompatibility	Pass	Unactivated Partial Thromboplastin Time
ASTM 756	Hemocompatibility	Pass	Hemolysis (complete)
USP <85>	LAL Endotoxin Test	Pass	LAL Endotoxin Quantitation Test (Kinetic-QCL Method)

### **Sterility, Shelf-life, and Packaging**

The Infuset™ Flow Control Extension Sets will be sterilized to a sterility assurance level (SAL) of  $10^{-6}$  and with a shelf life of 5 years.

### **Summary of Substantial Equivalence**

EMED Technologies Corporation Infuset™ Flow Control Extension Sets are substantially equivalent to the commercially available predicate device accessory in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Differences between the EMED Infuset™ Flow Control Extension Sets and the predicate do not raise any new issues of safety or effectiveness.

## Section 12: Substantial Equivalence Discussion

### Predicate Device Comparison

The following section compares the characteristics of EMED Infuset™ Flow Control Extension Sets to the RMS Precision Flow Rate Tubing Set predicates. A presentation of this information is provided immediately below, with a discussion of relevant points and conclusion following. Table 12-1 below provides a comparison of technological and other characteristics of the Infuset™ Flow Control Extension Sets and the predicate.

**Table 12-1**

	<b>Infuset™ Flow Control Extension Sets</b>	<b>RMS Precision Infusion Tubing Set (K933652)</b>
Indications for Use	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.	Intended for use with the RMS Freedom 60 Syringe Infusion Pump System to provide flow rate control to administer fluids from a container to a patient's vascular system.
Material	PVC	PVC
Design – Lengths	7.5 cm - 59 cm	34.3 cm - 100 cm
Design – components	Male Luer Lock Tubing Female Luer Lock Slide Clamp	Male Luer Lock Tubing Female Luer Lock Slide Clamp
Design – Approximate Residual Volume	0.10 – 0.20 ml	0.01 – 0.09 ml
Principle of Flow Rate Control	The internal fluid path dimensions of each Infuset configuration is fixed, thereby providing a single flow rate for each configuration.	The internal fluid path dimensions of each RMS flow rate tubing set configuration is fixed, thereby providing a single flow rate for each configuration.
Method of Sterilization	Ethylene Oxide (ETO)	Radiation

## **Discussion**

### Indications for Use Statement

The indications for use of the Infuset™ Flow Control Extension Sets and the predicate are essentially identical

### Materials

The materials that compose each Infuset™ Flow Control Extension Set were identified for their durability, performance, and biocompatibility characteristics. The PVC tubing selected is widely used for medical device applications, and is equivalent to that of the predicate. The materials used in the Infuset™ Flow Control Extension Sets are the same as those used in the predicate.

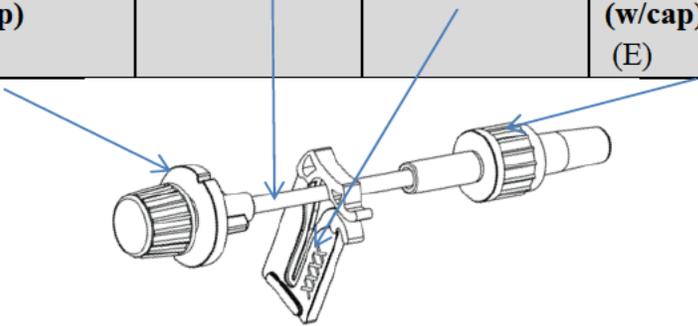
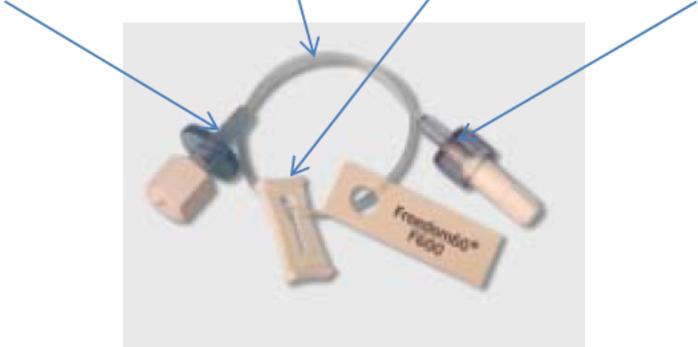
Biocompatibility of the Infuset™ Flow Control Extension Sets conform to ISO 10993 based on intended applications (see Section 15 and Appendix D) and material safety data is available for the Infuset™ Flow Control Extension Set components (see Appendix F).

### Design

The size and weight of the Infuset™ Flow Control Extension Sets and predicate are comparable. Infuset™ Flow Control Extension Sets are intended to be manufactured in several configurations to achieve flow control targets. The lengths of these configurations range from 7.5 cm to 59 cm. The predicates range in length from 34.3 – 100 cm, depending on the configuration and intended flow rate. Residual volumes of the two devices are similar and differences are can be attributed to differences in inner fluid path dimensions.

Table 12-2 below graphically identifies equivalent components in each Infuset™ Flow Control Extension Set and RMS Flow Rate Tubing Set. Following the table is a description of each including physical design, functional operation, and interface requirements.

**Table 12-2**

<b>Infuset™ Flow Control Extension Sets</b>	<b>Female Luer Connector (w/cap) (A)</b>	<b>Tubing (B)</b>	<b>Slide Clamp (C)</b>	<b>Male Luer Connector (w/cap) (E)</b>
				
<b>RMS Precision Flow Rate Tubing Set (K933652)</b>	<b>Female Luer Connector (w/cap) (A)</b>	<b>Tubing (B)</b>	<b>Slide Clamp (C)</b>	<b>Male Luer Connector (w/cap) (E)</b>
				

(A) and (E) Connectors – Both devices use standard luer lock connectors to connect the device to upstream fluid sources and downstream extension and/or patient sets. Infuset™ Flow Control Extension Set luer connectors comply with ISO 594 standards, and therefore ensure compatibility with other infusion sets used throughout industry, as well as the the BD Luer-Lok 60ml (reference #309653) syringe and the Sherwood Medical Monoject 60 ml (reference #8881-560125) syringe required for Freedom 60 use.

Related testing and validation activities are provided in Appendix D.

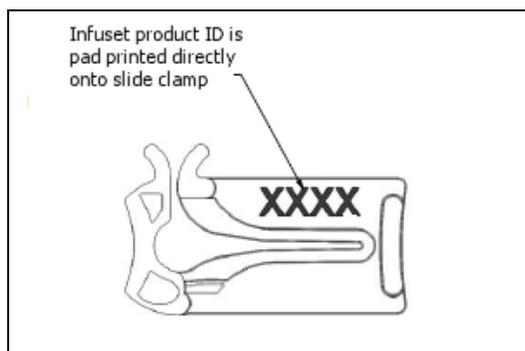
(B) Tubing – The purpose of the tubing is to provide a route for infusion fluid to flow between components of the device. Tubing length for configurations of Infuset™ Flow Control Extension Sets and the predicate flow rate accessory vary to meet target flow rates. The tubing of both the sets is bonded to the luer

locks connectors to assure leakage and strength requirements are achieved, per ISO 8536-8.

Related testing and validation activities are provided in Appendix D.

(C) Slide Clamp – The Infuset™ Flow Control Extension Sets are designed with a slide clamp to stop flow, as does the predicate. The predicate relies upon a separate label to indicate the product code, whereas the Infuset™ Flow Control Extension Set product code is printed directly onto the slide clamp, as demonstrated in Diagram 12-1 below:

**Diagram 12-1**



Any differences in design between the Infuset™ Flow Control Extension Sets and the predicate are not significant in relation to the intended uses of the devices, and do not impact safety, efficacy, or usability of the Infuset™ Flow Control Extension Sets.

### Principle of Action

Both the Infuset™ Flow Control Extension Sets and the predicate flow rate controllers rely on the length and cross-sectional area of the fluid path to control the flow rate. Both devices rely upon the flow controlling properties inherent to the static fluid path dimensions dictated by the tubing length and inner diameter to provide a precise, controlled flow rate. This follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rates of that fluid.

The principle by which both devices achieve flow control is identical in that both rely upon physical dimensions of their fluid paths to control the flow of fluid.

The net flow rate of the liquid through Infuset™ Flow Control Extension Sets and the predicates in real-world situations is derived from the force applied to the liquid, environmental factors, patient's physiological conditions, and viscosity of the fluid.

General Performance

Bench tests were performed using 0.9% saline solution to determine flow rate performance of Infuset™ Flow Control Extension Sets when used with the Freedom 60 Infusion Pump.

From this data target flow rate specifications were selected to ensure that Infuset™ Flow Control Extension Sets provide performance within 10% of stated target values. Table 12-3 below provides a summary of specified flow rates for select Infuset™ Flow Control Extension Set configurations determined through performance testing, accuracy specifications, and difference.

**Table 12-3**

Infuset	Specified Flow Rate (ml/hr)	Accuracy	%RSD
Infuset-190	(b)(4)		
Infuset-290			
Infuset-430			
Infuset-650			
Infuset-820			
Infuset-930			
Infuset-1850			

Testing also compared flow rate controlling abilities of the Infuset™ Flow Control Extension Sets to the RMS Precision Flow Rate Tubing Sets to establish that Infuset™ Flow Control Extension Sets provide flow rate control in line with that of the RMS Precision Flow Rate Tubing Set predicate configurations.

Table 12-4 below provides a summary of test results for RMS Precision Flow Rate Tubing Sets when used with the Freedom 60 infusion pump and 0.9% saline solution.

**Table 12-4**

RMS Set	Target Flow Rate (ml/hr)	Average Flow Rate (ml/hr)	Accuracy	%RSD
F45	(b)(4)			
F60				
F275				
F600				
F900				
F1200				
F2400				

Test results for each target rate are highly concentrated around the mean, as demonstrated by the low relative standard deviation (%RSD). This indicates a high level of precision for these devices – an equivalent level of precision as seen with the Infuset™ Flow Control Extension Sets. The varying magnitudes of difference between test data averages and nominal target values are noted; however, the reason is not known why published RMS Precision Tissue Set target values do not consistently align with empirical results.

It can be seen that the two devices both provide comparable flow rate control with equivalent high levels of precision, and therefore can be considered substantially equivalent in providing flow control to the Freedom 60 infusion system.

It is understood that flow rates can be affected by ambient temperature and patient conditions. The above flow rates were determined at controlled room temperature (20°C - 23°C) without any patient sets or additional tubing downstream of the Infuset™ Flow Control Extension Sets, and are intended to be used as starting points to determine the flow rate for individual patient, as determined by a healthcare professional.

Testing also concluded that the design of the Infuset™ Flow Control Extension Sets effectively interface with the Freedom 60 pump and compatible syringe in the same manner as the predicate RMS Precision Flow Rate Tubing Sets.

Additional studies were performed that verify the ability of the Infuset™ Flow Control Extension Sets to withstand pressures up to 25 psi. This level of pressure resistance is in compliance with ISO 8536-8, *Infusion equipment for medical use - Infusion equipment for use with pressure infusion apparatus*, and exceeds the claimed pressure of 15 psi provided by the Freedom 60 to provide a wide margin of safety.

The results of bench tests demonstrate the substantial equivalence of performance of the Infuset™ Flow Control Extension Sets to that of the predicate when used as indicated. Testing procedures and reports and record of other validation activities are provided in Appendix D.

## Sterilization

Infuset™ Flow Control Extension Sets are ETO sterilized to a sterility assurance level (SAL) of  $10^{-6}$  in accordance with ISO 11135-1 standard, whereas the predicate flow rate controller set achieves necessary sterility levels via radiation.

See Appendix C for additional information regarding the validated ETO sterilization process for Infuset™ Flow Control Extension Sets.

## **Conclusion**

The information presented above, derived from Infuset™ Flow Control Extension Sets material and finished product specifications, validation testing of various Infuset configurations and its components demonstrate that Infuset™ Flow Control Extension Sets are essentially equivalent in function, safety, performance, intended use, technology/principles and mechanical properties to the predicate.

Identified differences between the Infuset™ Flow Control Extension Sets and the predicate have been sufficiently evaluated and risks mitigated. Therefore, Infuset™ Flow Control Extension Sets do not raise any new issues of safety or effectiveness when compared to the predicate, and can be considered essentially equivalent.

## **Appendix 2: Extractables Testing**

This appendix contains the Infuset Extractables and Toxicity Risk Assessment and associated complete study reports for extractables testing. Included in the report is risk assessment of the identified residues as related to the intended use of the Infuset™ Flow Control Extension Set.









































































































































































































### **Appendix 3: Instructions for Use and Labeling**

This appendix contains the following:

<b>Exhibit</b>	<b>ID</b>	<b>Description</b>
1	AS-0010037	Artwork, Infuset-190 (representative example)
2	AS-0010041	Infuset IFU

3.750 in



# Infuset-190

Reorder No. / REF **FP-0010008**

Infusion extension set (en)    Dispositif de perfusion (fr)  
 Equipo de infusión (es)        Infusionset (de)  
 Set di infusione (it)            инфузионный набор (ru)  
 Infusionsset (sv)                Infusionsetti (fi)  
 Infusionsæt (da)                 Infusionssett (no)

← 51.76cm, ø0.3mm ID, ø2.4mm OD     ≈ **0.14ml**   
 Approximate priming volume.

QTY: <b>1 ea.</b> LOT XXXXXXXX	Manufacture Date: DD.MMM.YEAR Expiration Date: DD.MMM.YEAR
--------------------------------------	---

CAUTION.    Consult the instructions for use.    Do not use if package is damage.

**STERILE EO**    Do not re-use.    **Non-Pyrogenic**

This product is not made with di(2-ethylhexyl) phthalate (DEHP).  
 This product is not made with natural rubber latex.

-5°C    40°C  
 Storage temperature limits.

**RxOnly**    CE 0459

**CAUTION:** U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

**EC REP** European Representative:  
**Meridian Medical Ltd.**  
 Unit 1, Thorgate Road  
 Lineside Industrial Estate  
 Littlehampton, West Sussex BN17 7LU  
 Telephone: +44 (0) 1903 732 344  
 Fax: +44 (0) 1903 732 348  
 Email: admin@meridian-medical.com

**Manufactured for:**  
**EMED Technologies Corporation.**  
**Assembled in Mexico**  
**from US components.**  
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AS-0010037\_3.0-B

REVISION HISTORY			
REV	DCR#	CHANGE DESC.	DATE
1.0	12122011-01	INITIAL RELEASE	12/14/11
1.1	04182012-02	Updated REF# and Symbols	04/18/12
1.2	05182012-01	Changed MFG by to for: Added Assy in Mex.	05/18/12
2.0	10152012-01	Changed notes	11/15/12
3.0-A	12132013-02	Added symbols subtitles	12/13/12
3.0-B	03242014-02	(b)(4)	12/13/12

Notes (Unless Otherwise Specified)

1. COLOR: ARTWORK TO BE PRINTED IN BLUE PMS 285.

2. PRINT ARTWORK ON TYVEK SIDE OF POUCH.

3. POUCH SIZE: 3.75" X 8.00"

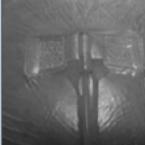
4. PRINT MANUFACTURE AND EXPIRATION DATE AND LOT NUMBER PER EMED'S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

**PROPRIETARY AND CONFIDENTIAL**  
 THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF EMED TECHNOLOGIES CORPORATION. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF EMED CORPORATION IS PROHIBITED.

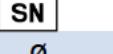
APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN.	Carlos G.	[ON FILE PER DCR]	03/24/14
ENG APPR.	Carlos G.	[ON FILE PER DCR]	03/24/14
CHECKED.			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	03/24/14

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TITLE:	<b>Artwork, Pouch, Infuset-190</b>	
ARTWORK #	AS-0010037	REV. 3.0-B

PICTURES	ENGLISH	FRENCH	SPANISH	GERMAN	ITALIAN
<p><b>WARNING:</b></p> 	<ul style="list-style-type: none"> <li>- Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.</li> <li>- Single use only; reuse can result in infection, and cross contamination</li> <li>- Do not re-sterilize</li> <li>- Replace at least every 48 hours</li> <li>- Use aseptic technique</li> <li>- Follow pharmacy / physician instructions</li> <li>- If fluid source is disconnected during the below steps, stop the process and place a sterile non-vented cap on syringe and set</li> <li>- Do not bend needle</li> <li>- <b>U.S. Federal Law restricts this device to sale by or on order of a physician</b></li> </ul>	<ul style="list-style-type: none"> <li>- Destiné à fournir perfusion sous-cutanée de la médecine d'une pompe à perfusion externe ou d'une seringue.</li> <li>- Usage unique, la réutilisation peut entraîner une infection, et la contamination croisée</li> <li>- Ne pas restériliser</li> <li>- Remplacer au moins toutes les 48 heures</li> <li>- Utiliser une technique aseptique</li> <li>- Suivez les instructions du médecin</li> <li>- Si la source de fluide est déconnecté pendant les étapes suivantes, arrêter le processus et placer un capuchon stérile non-ventilé sur la seringue et le tube</li> <li>- Ne pas plier l'aiguille</li> </ul>	<ul style="list-style-type: none"> <li>- Pensado para proporcionar una infusión subcutánea de la medicina de una bomba de infusión externa o una jeringa</li> <li>- Un solo uso, la reutilización puede dar lugar a infecciones y contaminación cruzada</li> <li>- No re-esterilizar</li> <li>- Reemplazar cada 48 horas</li> <li>- Utilice una técnica aseptica</li> <li>- Siga las instrucciones del médico</li> <li>- Si la fuente de líquido se desconecta durante los siguientes pasos, detenga el proceso y coloque un tapón estéril sin ventilación a la jeringa y otro al equipo</li> <li>- No doble la aguja</li> </ul>	<ul style="list-style-type: none"> <li>- Soll subkutane Infusion von Medikamenten von einem externen Infusionspumpe oder Spritze zu liefern.</li> <li>- Nur zum einmaligen Gebrauch;</li> <li>- Wiederverwendung kann in Infektion führen, und Kreuzkontamination</li> <li>- Nicht Wiedersterilisieren</li> <li>- Alle 48 Stunden ersetzen</li> <li>- Aseptik-Technik verwenden</li> <li>- Ärztliche Anweisungen beachten</li> <li>- Wenn kein Flüssigkeitsspender während der unten beschriebenen Prozeduren angeschlossen ist, muss dieser Prozess abgebrochen werden, eine sterile Kappe an der Spritze angebracht werden und der Vorgang von vorne wiederholt werden</li> <li>- Nadeln nicht biegen</li> </ul>	<ul style="list-style-type: none"> <li>- Destinato a fornire infusione sottocutanea di medicina da una pompa per infusione esterna o una siringa.</li> <li>- Solo monouso; riutilizzo può causare infezioni, e la contaminazione incrociata</li> <li>- Non sterilizzare</li> <li>- Sostituire almeno ogni 48 ore</li> <li>- Utilizzare una tecnica asettica</li> <li>- Seguire le istruzioni del medico</li> <li>- Se l'origine del liquido viene scollegato durante i passaggi qui sotto, arrestare il processo e mettere un tappo sterile senza sfiato sulla siringa e il tubo</li> <li>- Non piegare l'ago</li> </ul>
	<b>INSERTION</b>	<b>INSERTION</b>	<b>INSERCIÓN</b>	<b>EINSETZEN</b>	<b>INSERIMENTO</b>
1	 Wash hands before handling any supplies	Vous devez vous laver les mains avant de commencer	Lávese las manos antes de empezar	Vor Beginn Hände waschen	Lavarsi le mani prima di iniziare
2	 Remove tape from each needle tube (only when necessary)	Retirer le ruban de chaque tube aiguille (seulement si nécessaire)	Remueva la cinta de cada tubo de (sólo cuando sea necesario)	Entferne Schutzband von jeder Nadel	Togliere il nastro da ciascuna provetta ago (solo ove necessario)
3	 Load syringe	Remplir la seringue	Llene la jeringa	Spritze aufziehen	Riempire la siringa
	 Connect syringe (male luer lock) to SUB-Q set (female luer lock)	Connectez seringue et le dispositif	Conecte la jeringa al equipo	Spritze mit männlichem Luer Lock zu SUB-Q Set (weiblichen Luer Lock verbinden)	Collegare la siringa al dispositivo
4	 Prime set (be careful not to waste fluid)	Purger le dispositif (attention de ne pas perdre de liquide)	Purgue el equipo cuidando no desperdiciar líquido	Die Behandlungsschläuche mit der Spritze fluten, sodass Flüssigkeit aus den Nadeln fließen kann und sich keine Luft mehr in den Hohlräumen befindet	Purge dispositivo (attenzione a non sprecare fluido)
5	 Select site of insertion (which should be free from infection). Always choose a site at least 1" from the previous / other sites	Sélectionner un site d'insertion (qui doit être indemne d'infection). Toujours choisir un site au moins 2,5 cm des autres sites	Seleccione el sitio de inserción (que debe estar libre de infección). Elija siempre un sitio por lo menos a 2,5 cm de otros sitios	Die Stelle für die Insertion der Nadeln selektieren (Sie sollte frei von Infektionen sein) Der Einstich sollte immer ca. 2,5 cm von einer anderen Einstichstelle entfernt sein	Scegliere il sito di inserimento (che dovrebbero essere esenti da infezione). Scegliere sempre un sito di almeno 2,5 cm dal altri siti
6	 Clean site with antiseptic solution and wait until it dries (or approx. 1 minute)	Sèche nettoyer le site avec une solution antiseptique et attendre jusqu'à ce qu'il se dessèche (ou env. 1 minute)	Limpie el lugar con una solución antiséptica y espere hasta que se seque (Aprox. 1 minuto)	Einstichstelle mit Antiseptik Mittel reinigen und warten bis die Stelle trocken ist (ca. 1 Minute)	Pulire sito con soluzione antisettica e attendere che si asciugua (o ca. 1 minuto)
7	 Remove the wing protector and the needle guard (One needle at a time)	Enlevez la protection de l'aile et la protection de l'aiguille (Une aiguille à la fois)	Remueva el protector de las alas y el de la aguja (una sola aguja a la vez)	Den Flügelschutz der Nadel sowie den Spitzenschutz entfernen. (immer nur eine Nadel nach der anderen)	Rimuovere la protezione delle ali e la protezione dell'ago (un ago alla volta)
8	 Hold set by the wings allowing the needle to be exposed	Tenez fixé par les ailes permettant à l'aiguille d'être exposés	Coja las alas permitiendo que la aguja quede expuesta	Die Nadel bei den Schutzflügeln halten, sodass die Nadel frei heraussteht	Tenere insieme dalle ali permettendo l'ago di essere esposti
9	 Use thumb and index to pinch skin to increase subcutaneous layer thickness. Insert needle perpendicular to the skin to its fullest (until the base of the wings touches the skin).	Utilisez le pouce et l'index pour pincer la peau pour augmenter épaisseur de la couche sous-cutanée. Insérez l'aiguille perpendiculairement à la peau au maximum.	Utilice el dedo pulgar e índice para pellizcar la piel aumentando el grosor de la capa subcutánea. Inserte la aguja perpendicular a la piel (hasta que la base de las alas toque la piel).	Mit Daumen und Zeigefinger die Körperhaut zu einem Wulst drücken und die Nadel komplett einsetzen. Die Schutzflügel berühren damit die Haut.	Usare il pollice e l'indice per pizzicare la pelle per aumentare lo spessore strato sottocutaneo. Inserire l'ago perpendicolarmente alla cute, al massimo.
	 Place dressing over the wings	Fixer le ruban adhésif sur les ailes	Coloque el apósito sobre las alas.	Fixieren der Schutzflügel mittels eines Klebebands auf der Haut.	Laici nastro su ali

10		Make sure you are not injecting fluid into a blood vessel. To test this, attach a sterile syringe to the end of the infusion tubing.  Pull the plunger back gently. If you see any blood in the tubing, take the needle out of the injection site. Throw away the tubing and the needle and start over.	Veillez à ne pas injecter le liquide dans un vaisseau sanguin.  Pour tester cela, fixer une seringue stérile à la fin de la tubulure de perfusion. Tirez doucement sur le piston. Si vous voyez du sang dans le tube, retirez l'aiguille sur le site d'injection. Jeter le tube et l'aiguille et recommencer.	Asegúrese de que no se está inyectando el líquido en un vaso sanguíneo.  Para probar esto, conecte una jeringa estéril hasta el final del equipo de infusión. Tire del émbolo suavemente. Si ve sangre en el tubo, saque la aguja del lugar de la inyección. Deseche el tubo y la aguja y vuelva a empezar. Repita los pasos 5-10 con las otras agujas	Sicherstellen dass kein Blutgefäß angestochen wurde! Dazu mit der Spritze vorsichtig saugen. Falls Blut in den Schläuchen oder in der Spritze zu sehen ist, Nadel entfernen, mit einem Steril Mittel reinigen und einen anderen Einstichort wählen.  Fortsetzen mit Schritt 5-9	Fare attenzione a non iniettare liquidi in un vaso sanguigno. Assicurarasi che non sono l'iniezione del liquido in un vaso sanguigno.  Per verificare ciò, collegare una siringa sterile al tubo di infusione. Tirare lo stantuffo delicatamente. Se si vede sangue nel tubo, rimuovere l'ago dal sito di iniezione. Gettare via il tubo e l'ago e ricominciare.
11		Repeat steps 5-10 with other needles in set	Répétez les étapes 5-10 avec des autres aiguilles	Repita los pasos 5-10 con las otras agujas	Diese Schritte mit den anderen Nadeln wiederholen	Ripetere i passaggi 5-10 con gli altri aghi
12		Load syringe onto Infusion Pump following the instructions of the selected pump.	Mettez seringue sur la pompe et suivant les instructions de la pompe sélectionnée	Monte la jeringa en la Bomba de Infusión conforme a las instrucciones de la Bomba.	Die Spritze an einer Infusionspumpe anschließen und den Anweisungen des Infusionspumpenherstellers folgen	Carica siringa in pompa seguendo le istruzioni della pompa selezionata
<b>REMOVAL                      ENLEVEMENT                      REMOVER                      ENTFERNEN                      ESTRAZIONE</b>						
A		Remove dressing	Retirer le ruban adhésif	Remueva el apósito	Kleband von den Flügeln entfernen	Rimuovere medicazione
B		Take both wings and carefully pull needle straight up until needle is completely out of the skin	Prenez les deux ailes et tirez délicatement l'aiguille lorsque l'aiguille est complètement hors de la peau	Tome las dos alas y tire con cuidado la aguja hacia arriba hasta que la aguja esté completamente fuera de la piel	Die Nadel mit beiden Schutzflügeln aus der Haut ziehen	Prendete entrambe le ali ed estrarre l'ago fino a quando l'ago è completamente fuori della pelle
C		If using a SAF-Q set, carefully push the wings together while covering the needle with them	Si vous utilisez un dispositif SAF-Q, poussez délicatement les ailes ensemble tout en recouvrant l'aiguille avec eux	Si se está utilizando un equipo de SAF-Q, cierre las alas sobre la aguja con cuidado	Falls ein SAF-Q Set benutzt wird, die Flügel vorsichtig zusammendrücken und mit den Flügeln umschließen	Se si utilizza un set SAF-Q, con cura spingere le ali insieme, mentre copre l'ago con loro
D		Dispose in appropriate waste container	Disposer dans un contenant de récupération approprié	Descarte el equipo en un contenedor especial	Nadeln als Sondermüll entsorgen	Smaltire nel contenitore per i rifiuti del caso

	SYMBOLS	ENGLISH	FRENCH	SPANISH	GERMAN	ITALIAN
1		Warning	Attention	Advertencia	Warnung!	Attenzione
2		Read the instructions	Lisez les instructions	Lea las instrucciones	Bedienungsanleitung lesen!	Leggi le istruzioni
3		Do not re-use	Ne pas réutiliser	No vuelva a utilizar	Nur zur Einmalverwendung!	Non riutilizzare
4		Don't use if package is damaged	Ne pas utiliser lorsque l'emballage est endommagé	No utilizar cuando el envase esté dañado	Nicht verwenden wenn Packung beschädigt ist!	Non utilizzare quando l'imballaggio è danneggiato
5		Sterilized by Ethylene Oxide	Stérilisé par oxyde d'éthylène	Esterilizado por óxido de etileno	Sterilisation mit Äthylen Oxid	Sterilizzato con ossido di etilene
6		Manufacturer	Fabricant	Fabricante	Hersteller	Fabbricante
7		EC Representative	Représentant CE	Representante CE	EC Stelle	Rappresentante CE
8		Reference number	Numéro de référence	Número de referencia	Referenz Nummer	Numero di riferimento
9		Manufacturing date	Date de fabrication	Fecha de fabricación	Herstellungsdatum	Data di produzione
10		Batch	Lot	Lote	Los	Lotto
11		Expiration date	Date d'expiration	Fecha de caducidad	Verfallsdatum	Data di scadenza
12		Quantity	Quantité	Cantidad	Menge	Quantità
13		Storage temperature limits	Limites de température de stockage	Límites de temperatura de almacenamiento	Lagertemperatur Grenzen	Limiti de temperatura di stoccaggio
14		Serial number	Numéro de série	Número de serie	Seriennummer	Numero di serie
15		Diameter	Diamètre	Diámetro	Durchmesser	Diametro
16		Length	Longueur	Longitud	Länge	Lunghezza
17		To sale by or on the order of a physician.	Utiliser uniquement comme prescrit par un médecin	Utilice solamente según lo prescrito por un médico	Rezeptpflichtig	Utilizzare solo su ordine di un medico
18		Approximate priming volume	Approximative volume de remplissage	Volumen aproximado de llenado	Ungefähren füllvolumen	Approssimativo volume di riempimento
19		CE Mark	Marquage CE	Marca CE	CE-Kennzeichnung	Marchio CE
20		Non-pyrogenic fluid path	Trajet de fluide non-pyrogène	Apirógena fluido ruta	Nicht pyrogen Fluidweg	Apirogena fluido percorso

**Appendix 4: Material Safety Data Sheets (MSDS)**

This appendix contains the MSDS documents for the materials used in the manufacture and assembly of the Infuset™ Flow Control Extension Set, including plasticizers, lubricants, bonding agents, or other materials used in the manufacture of.

Exhibit	Material Description	Material Use
1	(b)(4)	
2		
3		
4		
5		





















































