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

Section 5. 510(k) Summary

K Number K140131

APR 03 2014

Submission Date: January 14, 2014

General Information

Classification	Class II
Trade Name	SUB-Q Subcutaneous Tissue Infusion Set
Common Name:	I.V. Administration Set
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Product Code and Class	FPA, Class II
Predicate Device	Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)
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

Purpose of Submission

This submission is intended to provide notification of modifications to our current legally marketed SUB-Q Subcutaneous Tissue Infusion Set device cleared under K020530. These modifications are the result of variations to the original device, resulting in a selection of infusion sets intended to satisfy individual user needs. Label changes are to reflect current corporate identity of the SUB-Q Subcutaneous Tissue Infusion Set.

Device Description

The EMED SUB-Q Subcutaneous Tissue Infusion Set (SUB-Q Set) device consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. Each infusion set has a luer lock at one end and a 90 degree 24g or 27g needle

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

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mounted to a standard or closing wing-stabilizer at the distal end of one or more lumens. Each lumen is connected by lengths of tubing and a number connectors, depending on configuration. The luer lock is used to connect to the infusion source. The needles are treated with medical grade silicone for ease of insertion into the skin. The device is for single use.

Intended Use

The SUB-Q Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

This is the same intended use as previously cleared for the Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530).

Technological Characteristics

The EMED SUB-Q Set has the same intended use as previously cleared for the predicate device (K020530).

The EMED SUB-Q Set incorporates the core design, same operating principle, and same materials as the predicate product (see K020530).

The EMED SUB-Q Set is assembled at the same facility as the predicate, under the same manufacturing processes as the predicate, and are tested against the same performance and batch release criteria as the predicate.

The EMED SUB-Q Set is packaged in the same manner using the same packaging materials and process as the predicate product (see K020530).

The EMED SUB-Q Sets are be sterilized to a sterility assurance level (SAL) of 10^{-6} using the same validated process as the predicate, and have the same specified storage conditions and 5 year shelf-life as the predicate (see K020530).

The EMED SUB-Q Set contains the following modifications to the predicate device (K020530):

- Various numbers of lumens were made available as configuration options.
- PVC bi-furcator and tri-furcator tubing connectors were added to the design to create from 2 to 6 lumens.
- 24g needle was made an available configuration option, with a corresponding change to tubing diameter.
- Needles received application of medical grade silicone lubricant to aid in insertion and increase patient comfort and satisfaction.
- Various needle lengths were made available configuration options
- Various tubing length variations were made available as configuration options.

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- A proprietary wing closure mechanism was made an available configuration option to aid in handling and disposal.
- Open end slide clamps to stop flow.
- Labeling updated to reflect the additional available configurations and current corporate identity (new ownership, logos, address, etc.).

The fundamental scientific technology, indications for use, materials, design, sterilization and packaging are not impacted by these changes, and remain identical between the proposed and predicate devices.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED SUB-Q Set and the predicate (K020530).

Table 5-1

	EMED SUB-Q Subcutaneous Tissue Infusion Set	**Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)**
Indications for Use	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.
Material/ Components	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC (std) and Polyproylene (locking) Connectors: PVC Needles: Stainless Steel Slide Clamp: ABS Bonding Agent: Loctite 3341	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC Connectors: None Needles: Stainless Steel Slide Clamp: None Bonding Agent: Loctite 3341
Device Length	Ranging from 2" - 36" (based on configuration)	42"
Tubing ID	0.200" (27g)	0.200" (27g)

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

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	EMED SUB-Q Subcutaneous Tissue Infusion Set	**Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)**
	0.260 (24g)	
Needle gage	24 gage and 27 gage	27 gage
Needle Lengths	Ranging from 6 mm - 16 mm (based on configuration)	6 mm
Number of Lumens	1 - 6	1
Wing type	Standard and Closing	Standard
Clamp Type	Slide	None
Needle Lubricant	Dow Corning 360 polydimethylsiloxane	None

Device Performance

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Non-clinical testing of the EMED SUB-Q Set included leakage, occlusion, and joint-strength which demonstrated the device meets the requirements for its intended use. The testing also demonstrates that the EMED SUB-Q Set meets performance criteria and is substantially equivalent to the predicate device as related to device performance.

Summary of Substantial Equivalence

The EMED Technologies Corporation SUB-Q Subcutaneous Tissue Infusion sets have the same basic design, fundamental scientific technology, indications for use, materials, sterilization, and packaging as the predicate, and therefore are substantially equivalent to the commercially available predicate device. Any differences between the EMED SUB-Q Subcutaneous Tissue Infusion Set and the predicate do not raise any new issues of safety or effectiveness.

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

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

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

April 3, 2014

EMED Technologies Corporation
C/O Peter Kollings
Director Regulatory Affairs and Quality Assurance
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762

Re: K140131
Trade/Device Name: SUB-Q Subcutaneous Tissue Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 10, 2014
Received: March 12, 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.

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

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

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

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

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)*
K140131

Device Name
SUB-Q Subcutaneous Tissue Infuset Set

Indications for Use *(Describe)*
SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

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: 2014.04.03
10:58:53 -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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 3, 2014

EMED Technologies Corporation
C/O Peter Kollings
Director Regulatory Affairs and Quality Assurance
1264 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762

Re: K140131
Trade/Device Name: SUB-Q Subcutaneous Tissue Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 10, 2014
Received: March 12, 2014

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Sincerely yours,

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

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

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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)*
K140131

Device Name
SUB-Q Subcutaneous Tissue Infuset Set

Indications for Use *(Describe)*
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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: 2014.04.03
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

Collins, Virginia *

From: Collins, Virginia *
Sent: Friday, April 04, 2014 3:01 PM
To: 'pkollings@emedtc.com'
Cc: DCCLetters
Subject: K140131 SE Letter
Attachments: K140131.pdf

Tracking:	**Recipient**	**Delivery**
	'pkollings@emedtc.com'	
	DCCLetters	Delivered: 4/4/2014 3:01 PM

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

4

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K140131

FDA CDRH DMC
JAN 28 2014
Received

January 27, 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: *SUB-Q Subcutaneous Tissue Infusion Set* (K140131) - Replacement eCopy

The attached CD contains a replacement eCopy of K140131, *SUB-Q Subcutaneous Tissue Infusion Set*. The included replacement eCopy is an exact duplicate of the paper copy dated January 14, 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

1 CD

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

1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.0071 • Fax 916.932.0074 • www.emedtc.com

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EMED Technologies

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K140131

January 14, 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

FDA CDRH DMC
JAN 17 2014
Received

Re: 510(k) Premarket Notification
SPECIAL

SUB-Q Subcutaneous Tissue Infusion Set

EMED Technologies Corporation hereby submits this **Special 510(k): Device Modification** to request modifications to our SUB-Q Subcutaneous Tissue Infusion Set (K020530).

The modifications to K020530 are intended to meet user needs while maintaining the same basic design, fundamental scientific technology, and intended use.

We believe these modifications are eligible for the Special 510 (k) process since they do not alter the fundamental scientific technology or intended use of the subject device of K020530.

EMED considers the intent to market the SUB-Q Subcutaneous Tissue Infusion Set 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: SUB-Q Subcutaneous Tissue Infusion Set

Common Name: I.V. Administration Set

Classification Name and Reference:

Intravascular Administration Set

21 CFR §880.5440

4

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.0071 • Fax 916.932.0074 • www.emedtc.com

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

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

Intended Use:	SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.
Proposed Regulatory Class:	Class II
FDA Panel:	General Hospital
Device Product Code:	FPA

Design and Use of the Device

The SUB-Q Subcutaneous Tissue Infuset Set is a disposable device intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The SUB-Q Subcutaneous Tissue Infuset Set can be connected to other commercially available I.V. administration sets and fluid sources utilizing standard luer lock connectors.

Design and Use of the Device

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

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

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EMED Technologies

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Thank you for your review of this Special 510(k) pre-market notification.

Regards,

Peter Kollings

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

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

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916 932 0871 • Fax 916 932 0874 • www.emedtc.com

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

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

510 (k) Premarket Notification – Special

SUB-Q Subcutaneous Tissue Infusion Set

Applicant: EMED Technologies Corporation

Peter Kollings

Director of Regulatory Affairs and Quality Assurance

1264 Hawks Flight Ct. Ste. 200

El Dorado Hills, Ca 95762

Phone: 916.632.0071 x114

Fax: 916.932.0074

pkollings@emedtc.com

Submission Date: January 14, 2014

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

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

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

Section 1: Medical Device User Fee Cover Sheet

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

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

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
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
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: http://www.fda.gov/oc/mdufma/coversheet.html

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

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****8533

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)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: 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?
[X] 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.)
[ ] 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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).
[ ] YES [X] 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) [redacted] 02-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

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

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*

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

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

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

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
01/14/2014

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)

SUB-Q Subcutaneous Tissue Infusion Set

SUB-Q Set

SUB-Q Set

SUB-Q Subcutaneous Infusion Set

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 Assuance

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
01/14/2014

PSC Graphics: (301) 443-1090 EF

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

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

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.

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/14/2014	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☑ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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 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:

PSC Graphics: (301) 443-1090 EF

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

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

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

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

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

- ☐ Response to FDA correspondence:

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

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

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

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

☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☑ Other Reason *(specify):*

Minor specifciation changes and design modicifcations that do not affect the device's intneded use or alter the device's fundamantal scientific technology.

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

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

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FPA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K020530	1	SUB-Q Subcutaneous Tissue Infusion Set	1	EMED Technologies
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Intravascular Administration Set

	Trade or Proprietary or Model Name for This Device		Model Number
1	SUB-Q Subcutaneous Tissue Infusion 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	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FPA

C.F.R. Section *(if applicable)*: 21 CFR 880.5440

Classification Panel: General Hospital

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

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

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

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

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

☑ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☑ Contract Sterilizer ☑ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifer (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

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

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

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

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 11135-1	ISO	ETO Sterilization	2007	
2	ISO 14971	ISO	Application of Risk Managmenet to Medical Devices	2007	
3				2003	
4				1986	
5				1998	
6					
7					

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

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

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

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

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

Records processed under FOIA Request # 2015-8342; Released by CDRH on 02-22-2016
Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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 [1]

ISO 14971-2007: Application of Risk Management to Medical Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-40		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] 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) [5]?	☐	☐
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 [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☑

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] 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.

[5] 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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

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

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* 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.

❖ 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.

Paperwork Reduction Act Statement

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:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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 [1]

ISO 11135:2007, ETO Sterilization

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-228		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] 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) [5]?	☐	☐
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 [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] 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.

[5] 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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* 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.

❖ 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.

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Section 3: 510k Cover Letter

This section contains completed FDA 510k Cover Letter

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EMED Technologies
The power of creative thinking

January 14, 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
SPECIAL

SUB-Q Subcutaneous Tissue Infusion Set

EMED Technologies Corporation hereby submits this **Special 510(k): Device Modification** to request modifications to our SUB-Q Subcutaneous Tissue Infusion Set (K020530).

The modifications to K020530 are intended to meet user needs while maintaining the same basic design, fundamental scientific technology, and intended use.

We believe these modifications are eligible for the Special 510 (k) process since they do not alter the fundamental scientific technology or intended use of the subject device of K020530.

EMED considers the intent to market the SUB-Q Subcutaneous Tissue Infusion Set 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: SUB-Q Subcutaneous Tissue Infusion Set

Common Name: I.V. Administration Set

Classification Name and Reference:

Intravascular Administration Set

21 CFR §880.5440

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.9071 • Fax 916.932.9074 • www.emedtc.com

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Intended Use:	SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.
Proposed Regulatory Class:	Class II
FDA Panel:	General Hospital
Device Product Code:	FPA

Design and Use of the Device

The SUB-Q Subcutaneous Tissue Infuset Set is a disposable device intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The SUB-Q Subcutaneous Tissue Infuset Set can be connected to other commercially available I.V. administration sets and fluid sources utilizing standard luer lock connectors.

Design and Use of the Device

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

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Thank you for your review of this Special 510(k) pre-market notification.

Regards,

Peter Kollings
Director Regulatory Affairs and Quality Assurance
EMED Technologies Corporation

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

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.9071 • Fax 916.932.9074 • www.emedtc.com

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Section 4. Indications for Use Statement

510(k) Number (if known):	[TBD]
Device Name:	SUB-Q Subcutaneous Tissue Infuset Set
Indications for Use:	SUB-Q Subcutaneous Tissue Infuset Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5. 510(k) Summary

K Number _____

Submission Date: January 14, 2014

General Information

Classification	Class II
Trade Name	SUB-Q Subcutaneous Tissue Infusion Set
Common Name:	I.V. Administration Set
Classification Name and Reference:	Intravascular Administration Set 21 CFR §880.5440
Product Code and Class	FPA, Class II
Predicate Device	Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)
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

Purpose of Submission

This submission is intended to provide notification of modifications to our current legally marketed SUB-Q Subcutaneous Tissue Infusion Set device cleared under K020530. These modifications are the result of variations to the original device, resulting in a selection of infusion sets intended to satisfy individual user needs. Label changes are to reflect current corporate identity of the SUB-Q Subcutaneous Tissue Infusion Set.

Device Description

The EMED SUB-Q Subcutaneous Tissue Infusion Set (SUB-Q Set) device consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. Each infusion set has a luer lock at one end and a 90 degree 24g or 27g needle

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mounted to a standard or closing wing-stabilizer at the distal end of one or more lumens. Each lumen is connected by lengths of tubing and a number connectors, depending on configuration. The luer lock is used to connect to the infusion source. The needles are treated with medical grade silicone for ease of insertion into the skin. The device is for single use.

Intended Use

The SUB-Q Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

This is the same intended use as previously cleared for the Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530).

Technological Characteristics

The EMED SUB-Q Set has the same intended use as previously cleared for the predicate device (K020530).

The EMED SUB-Q Set incorporates the core design, same operating principle, and same materials as the predicate product (see K020530).

The EMED SUB-Q Set is assembled at the same facility as the predicate, under the same manufacturing processes as the predicate, and are tested against the same performance and batch release criteria as the predicate.

The EMED SUB-Q Set is packaged in the same manner using the same packaging materials and process as the predicate product (see K020530).

The EMED SUB-Q Sets are be sterilized to a sterility assurance level (SAL) of 10^{-6} using the same validated process as the predicate, and have the same specified storage conditions and 5 year shelf-life as the predicate (see K020530).

The EMED SUB-Q Set contains the following modifications to the predicate device (K020530):

- Various numbers of lumens were made available as configuration options.
- PVC bi-furcator and tri-furcator tubing connectors were added to the design to create from 2 to 6 lumens.
- 24g needle was made an available configuration option, with a corresponding change to tubing diameter.
- Needles received application of medical grade silicone lubricant to aid in insertion and increase patient comfort and satisfaction.
- Various needle lengths were made available configuration options
- Various tubing length variations were made available as configuration options.

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- A proprietary wing closure mechanism was made an available configuration option to aid in handling and disposal.
- Open end slide clamps to stop flow.
- Labeling updated to reflect the additional available configurations and current corporate identity (new ownership, logos, address, etc.).

The fundamental scientific technology, indications for use, materials, design, sterilization and packaging are not impacted by these changes, and remain identical between the proposed and predicate devices.

Table 5-1 below provides a comparison of technological and other characteristics of the EMED SUB-Q Set and the predicate (K020530).

Table 5-1

	EMED SUB-Q Subcutaneous Tissue Infusion Set	**Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)**
Indications for Use	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.	Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. The device is supplied sterile, for singly use only. It is a prescription device.
Material/ Components	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC (std) and Polyproylene (locking) Connectors: PVC Needles: Stainless Steel Slide Clamp: ABS Bonding Agent: Loctite 3341	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC Connectors: None Needles: Stainless Steel Slide Clamp: None Bonding Agent: Loctite 3341
Device Length	Ranging from 2" - 36" (based on configuration)	42"
Tubing ID	0.200" (27g)	0.200" (27g)

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	EMED SUB-Q Subcutaneous Tissue Infusion Set	Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)
	0.260 (24g)	
Needle gage	24 gage and 27 gage	27 gage
Needle Lengths	Ranging from 6 mm - 16 mm (based on configuration)	6 mm
Number of Lumens	1 - 6	1
Wing type	Standard and Closing	Standard
Clamp Type	Slide	None
Needle Lubricant	Dow Corning 360 polydimethylsiloxane	None

Device Performance

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Non-clinical testing of the EMED SUB-Q Set included leakage, occlusion, and joint-strength which demonstrated the device meets the requirements for its intended use. The testing also demonstrates that the EMED SUB-Q Set meets performance criteria and is substantially equivalent to the predicate device as related to device performance.

Summary of Substantial Equivalence

The EMED Technologies Corporation SUB-Q Subcutaneous Tissue Infusion sets have the same basic design, fundamental scientific technology, indications for use, materials, sterilization, and packaging as the predicate, and therefore are substantially equivalent to the commercially available predicate device. Any differences between the EMED SUB-Q Subcutaneous Tissue Infusion Set and the predicate do not raise any new issues of safety or effectiveness.

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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.

Peter Kollings
(Signature)

Peter Kollings
(Typed Name)

1/14/14
(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].

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

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Section 7: Class III Summary and Certifications

The EMED SUB-Q Subcutaneous Tissue Infuset Set is a Class II device and therefore this section is not applicable.

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Section 8: Financial Certification or Disclosure Statement

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

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Section 9. Declaration of Conformity and Summary Reports

As required by 21 CFR §807.87(g)

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Additionally, to the best of my knowledge, EMED Technologies Corporation, is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

(Signature)

Peter Kollings
(Printed Name)

1/14/14
(Dated)

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

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Section 10: Device Description and Substantial Equivalence

Device Description

The EMED SUB-Q Subcutaneous Tissue Set (SUB-Q Set) device consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place.

Each infusion set has a rigid PVC luer lock at one end and a 90 degree 24g or 27g stainless steel needle mounted to a PVC wing-stabilizer at the distal end of one or more lumens. The wing-stabilizer is provided in either standard or closing variations based on the specified SUB-Q Set configuration.

SUB-Q Sets are configured to provide from 1 to 6 lumens, with each lumen created through lengths of tubing and a number connectors, depending on configuration. Multiple lumens are created through incorporation of biconnectors or triconnectors into the design. For example, use of a single bi-connector would provide two resulting lumens with needles at the end of each, while use of a combination of two biconnectors and two triconnectors provide a total of 6 lumens. See Diagram 10-1 below for examples.

Diagram 10-1

(b)(4)

[redacted]

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(b)(4)

[redacted]

A standard female luer lock is used to connect to the infusion source.

The needles are stainless steel and are treated with medical grade liquid silicone (Dow Corning 360 polydimethylsiloxane) for ease of insertion into the skin. Coating needles with medical grade silicone is widely used throughout industry as a means to improve insertion properties of hypodermic needles.

The SUB-Q Set is comprised of the components listed in Table 10-1 below, with detailed specifications and drawing found in Appendix B.

Table 10-1

Component	Description
Female Luer Lock	Rigid PVC
Female Luer Cap	Rigid PVC (removed before use)
Tubing	27g – (b)(4) [redacted] (b)(4) Lengths of 2" – 36" 24g - (b)(4) [redacted] (b)(4) Lengths of 2" – 36"
Biconnector and Triconnector	(b)(4) [redacted]
Slide Clamp	(b)(4) [redacted] ABS, Open End Slide Clamp
Wing	PVC: (b)(4) [redacted]
Needle	90 degree bent needle, 27g and 24g, (b)(4) [redacted]
Bonding Agent	Loctite 3341 Light Cure Acrylic Adhesive

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The SUB-Q set is a single use device that will be provided sterile. The SUB-Q Sets will be sterilized to a sterility assurance level (SAL) of 10^{-6} in compliance with ISO 11135 requirements. The validated sterilization process utilizes the overkill approach to ETO sterilization (ISO 11135-1, Annex B).

Substantial Equivalence Discussion

The indications for use have not changed as a result of the modifications discussed in this submission. The EMED SUB-Q Set has the same intended use as previously cleared for the predicate device (K020530).

The EMED SUB-Q Set incorporates the core design, same operating principle, and same materials as the predicate product (see K020530).

The EMED SUB-Q Set is assembled at the same facility as the predicate, under the same manufacturing processes as the predicate, and are tested against the same performance and batch release criteria as the predicate.

The EMED SUB-Q Set is packaged in the same manner using the same packaging materials and process as the predicate product (see K020530).

The EMED SUB-Q Sets are be sterilized to a sterility assurance level (SAL) of 10^{-6} using the same validated process as the predicate, and have the same specified storage conditions and 5 year shelf-life as the predicate (see K020530).

A presentation of select characteristics of the EMED SUB-Q Set as compared to the predicate (K020530) is provided in Table 10-2 below to demonstrate additional similarities as well as minor modifications. A discussion of relevant points and conclusions follows.

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Table 10-2

	EMED SUB-Q Subcutaneous Tissue Infusion Set	Evans SUB-Q Subcutaneous Tissue Infusion Set (K020530)
Materials	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC (std) and Polyproylene (locking) Connectors: PVC Needles: Stainless Steel Slide Clamp: ABS Bonding Agent: Loctite 3341	Biocompatible, non-toxic materials widely used in medical products, such as: Luer: PVC Luer Cap: Polypropylene Tubing: PVC Wings: PVC Connectors: None Needles: Stainless Steel Slide Clamp: None Bonding Agent: Loctite 3341
Length	Ranging from 2" - 36" (based on configuration)	42"
Tubing OD	0.080" (27g and 24g)	0.080" (27g)
Tubing ID	0.200" (27g) 0.260 (24g)	0.200" (27g)
Needle gage	24 gage and 27 gage	27 gage
Needle Lengths	Ranging from 6 mm - 16 mm (based on configuration)	6 mm
Number of Lumens	1 - 6	1
Wing type	Standard and Closing	Standard
Clamp Type	Slide	None
Needle Lubricant	Dow Corning 360 polydimethylsiloxane	None

Materials

All fluid path component materials are the same. Tubing and connectors (luer and multi-lumen) remain PVC, bonding agent remains the same, and needles are of the same stainless steel material and composition originally found in the predicate device (K020530).

Stabilizing wings are non-fluid path contacting components made out of materials widely used in industry. The standard stabilizing wings are PVC and the locking mechanism incorporated into the locking stabilizing wings is polypropylene.

Slide Clamps are non-fluid path contacting components manufactured out of ABS. ABS is known and widely used in industry for I.V. administrative set componentry.

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Dow Corning 360 polydimethylsiloxane is hydrophobic lubricant for medical devices used due to its good stability over a broad range of temperatures, tolerance of ETO sterilization cycles, low toxicity/skin sensitization, and excellent lubricating characteristics. The target application of this silicone fluid is for lubrication and siliconization of glass, plastics, rubbers, and metals. The application of Medical grade liquid silicone to hypodermic needles to provide lubricity and aid in insertion is a common practice in industry.

MSDS documents for fluid path contacting materials or components not found in the original predicate device are provided in Appendix B, Specifications and MSDS.

Device Design and Principles of Action

The fundamental design of the EMED SUB-Q Set is equivalent to that of the K052530 predicate. In both devices the infusion set has a rigid PVC luer lock at one end and a 90 degree stainless steel needle mounted to a PVC wing-stabilizer at the distal end of each lumen.

The essentially equivalent fundamental design of EMED SUB-Q Set and the predicate is demonstrated in Diagram 10-2 below.

Diagram 10-2

(b)(4)

[redacted]

It can be seen that both devices are comprised of the same basic components and follow the same general design in that luer locks are used to attach the set to the fluid source, tubing is used to transfer the fluid, stabilizer wings are provided to assist in needle handling, and hypodermic needles are used to ultimately deliver the infused

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liquid subcutaneously. The minor modifications and additions to the physical design of the predicate are identified and discussed below:

Number of lumens – The EMED SUB-Q Set provide from 1 to 6 lumens using biconnectors and triconnectors. The increased number of lumens provides prescribers and patients with several administration set configurations to best meet each individuals therapeutic need without relying upon the use of additional extension sets. The minor modification of adding additional lumens to the predicate design does not impact the indications for use or the fundamental design of the predicate.

PVC biconector and triconnector tubing connectors – The EMED SUB-Q Set provide from 1 to 6 lumens using biconnectors and triconnectors. A biconnector and triconnector can be used to divide the fluid path of a single lumen into 2 or 3 lumens, with various combinations of biconnectors and triconnectors used to achieve desired number of lumens.

Tubing is bonded to a connector using the same bonding agent as used to connect the tubing to the luer lock. The connectors do not adversely impact delivery of the infused fluid as their effective internal ID is equivalent to that of the tubing.

Biconnectors and triconnectors are made from (b)(4) [redacted] Rigid PVC. Natural latex rubber is not used in the manufacture or assembly of these two products. The raw materials used for these two products do not contain DEHP, nor is it used in their manufacture or assembly. These components are made from materials widely used in the medical device industry for infusion sets, and their use does not impact label statements made regarding DEHP or use of natural latex rubber in their manufacture. See Appendix B, Specifications and MSDS for additional detail.

The minor modification of adding additional PVC connectors to the predicate design does not impact the indications for use or the fundamental design of the predicate.

24g needle – The 24g needle was selected to provide prescribers and patients an alternative to the 27g needle found in the predicate that would allow for increased infusion rates for more viscous liquid medicines. SUB-Q sets with the 24g configuration and the corresponding tubing diameter also provide users with increased flow rates as compared to the 27g for the same given solution. The minor modification of adding an industry standard needle gauge does not impact the indications for use or the fundamental design of the predicate.

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Increased Tubing ID – This design modification was necessary to accommodate the slightly larger outer diameter of the 24g needle option discussed above. The material, manufacturing, handling, and assembly of EMED SUB-Q Sets with 24g needles and corresponding tubing are identical to that of the predicate, and therefore do not impact the indications for use or the fundamental design of the predicate.

Needle lengths – Various needle lengths are provided to accommodate anatomic variations of patients and allow patients flexibility in selecting infusion sites and/or infusion site rotations. The material, manufacturing, handling, and assembly of EMED SUB-Q Sets across all needle length configurations are identical to that of the predicate, and therefore do not impact the indications for use or the fundamental design of the predicate.

Tubing lengths – Various tubing lengths are provided to accommodate customer and user preferences. The material, manufacturing, handling, and assembly of EMED SUB-Q Sets across all tubing length configurations are identical to that of the predicate, and therefore do not impact the indications for use or the fundamental design of the predicate.

Proprietary stabilizer wing closure mechanism – (b)(4) [redacted]

(b)(4) [redacted]

Open end slide clamps – Addition of the open end slide clamp was in response to customer requests for a means to stop flow to a single lumen while flow to remaining lumens can continue. Flow control sets, infusion pumps, and other infusion apparatus typically have the means to stop all flow to the SUB-Q Set, but cannot selectively stop flow to a single site. Open end slide clamps of this type or used throughout industry to allow the user to stop flow through a soft-walled tube. This user requirement was evaluated and determined to providing the patient valuable control over their therapy without impacting the indications for use or the fundamental design of the predicate.

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Dow Corning 360 polydimethylsiloxane – This is hydrophobic lubricant for medical devices used due to its good stability over a broad range of temperatures, tolerance of ETO sterilization cycles, low toxicity/skin sensitization, and excellent lubricating characteristics. The target application of this silicone fluid is for lubrication and siliconization of glass, plastics, rubbers, and metals. The application of Medical grade liquid silicone to hypodermic needles to provide lubricity and aid in insertion is a common practice in industry. The minor modification of applying medical grade liquid silicone to SUB-Q Sets needles does not impact the indications for use or the fundamental design of the predicate.

Risk Analysis performed on the SUB-Q Set regarding the above minor modifications is discussed in Section 12, Risk Analysis and Design Controls.

Conclusion

The basic design, fundamental scientific technology, indications for use, materials, sterilization, and packaging are not impacted by modifications discussed in this section, and remain identical between the EMED SUB-Q Set and the predicate devices

Based on the above information, the EMED SUB-Q Sets are substantially equivalent to the commercially available predicate device in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Any differences between the EMED SUB-Q Set and the predicate do not raise any new issues of safety or effectiveness.

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Section 11: Proposed Labeling

Changes to the predicate labeling are to reflect the additional available configurations and minor design modifications of the EMED SUB-Q Tissue Infusion Sets, and to be consistent with the current EMED corporate identity (colors, logos, address, etc.)

The indications for use for the SUB-Q Tissue Infusion Sets have not changed as a result of the modifications described in this submission. Examples of proposed labeling reflecting such modifications are contained in Appendix A.

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Section 12: Risk Analysis and Design Controls

Impact of the minor modifications made to the predicate described in section 010, Device Description and Substantial Equivalence were carefully evaluated to assess and mitigate potential safety and effectiveness concerns regarding the device. Risk Analysis of SUB-Q Tissue Infusion Sets with the modifications was performed per EMED internal procedures in line with FMEA analysis techniques described in ISO 14971.

The minor modifications made to the predicate relating to changes to physical dimensions such as length, inner diameter, and outer diameter and addition of non-fluid path contacting accessories, were evaluated and found to present insignificant additional risk to the user when compared to the predicate.

These minor modifications presented insignificant impact to manufacturing and assembly as well, in that critical assembly steps (assembly of tubing and connectors, validated UV-bonding, packaging, validated ETO sterilization) are the same as used in the assembly of the predicate and will remain unchanged.

The same Final Product Test methods and acceptance criteria applied to the predicate will be applied to each finished lot of the EMED SUB-Q products prior to commercial release. This ensures that the finished product incorporating the minor modifications will provide the same performance as the predicate. Finished Product Testing includes evaluation of leakage, occlusion, and visual defects from a random sample of production units. Sample sizes and acceptance criteria for each test attribute (b)(4) [redacted] (b)(4) [redacted] and are based on total lot size and criticality of the attribute.

Based on the insignificant impact to the overall manufacturing process, use of established and validated assembly and processing steps, and comprehensive Finished Product Release testing, it was established that additional validation activities were not warranted.

Introduction of bi-connectors and tri-connectors into the SUB-Q design did not introduce increased risk due to the materials and bonding agents being equivalent to those used in the predicate, and therefore does not affect the general technical characteristics of the product or its intended use. As stated above, the same UV- bonding, assembly, packaging, sterilization, and Finished Product testing processes associated with the predicate will be applied to the EMED SUB-Q Tissue Infusion sets, thus ensuring the minor modification of adding the biconnector and triconnectors to the design results in devices of the same quality and performance as the predicate. The materials and design of the biconnectors and triconnectors are further discussed in Section 10, Device Description and Substantial Equivalence.

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The addition of Dow Corning 360 medical grade liquid silicone was established as a safe and effective needle lubricant used throughout industry, as supported by material information sheets and material safety data (see Appendix B). Development tests were performed that confirmed production-equivalent application of the silicone lubricant consistently provided decreased penetration force for needle insertion. With the information provided by the supplier and that found in published and public literature, sufficient evidence was available to establish that the addition of Dow Corning 360 silicone lubricant to the predicate design is a minor modification that performs as intended and poses insignificant risk to the user as compared to the predicate.

Conclusion

Design control and risk management activities were performed to evaluate the minor modifications to the predicate, to establish the residual risk related to the modifications, and perform any necessary actions to decrease residual risk to acceptable levels. These actions resulted in a design that is substantially equivalent to the commercially available predicate device in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Any differences between the EMED SUB-Q Tissue Infusion Set and the predicate do not raise any new issues of safety or effectiveness.

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Appendix A: Instructions for Use and Labeling

This appendix contains the following:

- Exhibit 1: ER-0064, SUB-400 pouch (representative example)
- Exhibit 2: AS-0010003, SUB-Q IFU
- Exhibit 3: ER-0014, SUB-400 inner box label (representative example)

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REVISION HISTORY			
REV.	DCN#	CHANGE DESC.	DATE
1.2	-	INITIAL RELEASE	07/29/10
2.0	05032012-01	ADDED SOFT-GLIDE AND NEW SYMBOLS	05/04/12
2.1	05152012-01	Changed MFG for: & added Assy. In Mex.	05/15/12
3.0-A	12132013-02	Removed (SCIg) and Added subtitles to symbols.	12/13/13

Peel Down

Soft-Glide™

Reorder No. / REF SUB-400

Subcutaneous infusion set (EN)
Dispositif de perfusion sous-cutanée (FR)
Dispositivo de infusión subcutánea (ES)
Subkutanes Infusionsset (DE)
Dispositivo di infusione sottocutanea (IT)

Ø2.0 mm OD 0.5 mm ID ⟷ 91.5 cm [36"]

QTY: 1 ea.	4 Needles / Aiguilles / Agujas / Nadeln / Aghi Ø27Ga. ⟷ 6 mm	Priming Volume / Volume de remplissage / Volumen de llenado / Füllvolumen / Volume di riempimento < 0.8 ml

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

DEHP NO — This product is not made with di(2-ethylhexyl) phthalate.

STERILE EO — Non-Pyrogenic

Latex NO — This product is not made with natural rubber latex.

CE 0459

40°C / -5°C Storage temperature limits.

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

Manufacture Date: DD.MMM.YEAR

Use By: DD.MMM.YEAR

LOT XXXXXXX

INSTRUCTIONS FOR USE:
1. Connect Female Luer to source of infusion.
2. Prime infusion set
3. Use each wing to hold set and insert each needle into the skin.
4. Replace per CDC guidelines

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

EMED Technologies
The power of creative thinking

Manufactured for:
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El Dorado Hills, CA 95762 USA
Telephone: +(1) 916.932.0071
Fax: +(1) 916.932.0074
Email: info@emedtc.com
Website: www.emedtc.com

ER-0064_3.0-A

Notes (Unless Otherwise Specified)
1. COLOR: ARTWORK TO BE PRINTED IN BLUE PMS 285.
2. PRINT ARTWORK ON TYVEK SIDE OF POUCH CENTER HORIZONTAL.
3. POUCH SIZE: 6" X 10"
4. PRINT MANUFACTURE DATE, EXPIRATION DATE 5 YEARS FROM MFG 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]	12/13/2013
CHECKED			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/2013
ENG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/2013
Q.A			

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El Dorado Hills CA 95762
Tel. 916.932.0071

TITLE. Pouch, Artwork label, SUB-400
REV. 3.0-A
ARTWORK No. ER-0064
SIZE: A | SCALE: 1:1 | SHEET 1 OF 1 | TEMPLATE NO. MF-0022 REV 1.3

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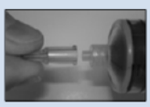
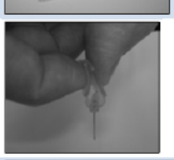
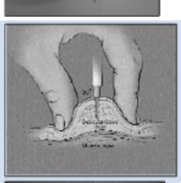
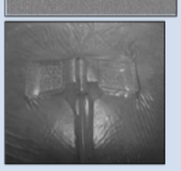
EMED Technologies Corporation

SUB-Q set instructions for use

PICTURES	ENGLISH	FRENCH	SPANISH	GERMAN	ITALIAN
WARNING:	- Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. - Single use only; reuse can result in infection, and cross contamination - Do not re-sterilize - Replace at least every 48 hours - Use aseptic technique - Follow pharmacy / physician instructions - If fluid source is disconnected during the below steps, stop the process and place a sterile non-vented cap on syringe and set - Do not bend needle - **U.S. Federal Law restricts this device to sale by or on order of a physician**	- Destiné à fournir perfusion sous-cutanée de la médecine d'une pompe à perfusion externe ou d'une seringue. - Usage unique, la réutilisation peut entraîner une infection, et la contamination croisée - Ne pas restériliser - Remplacer au moins toutes les 48 heures - Utiliser une technique aseptique - Suivez les instructions du médecin - 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 - Ne pas plier l'aiguille	- Pensado para proporcionar una infusión subcutánea de la medicina de una bomba de infusión externa o una jeringa - Un solo uso, la reutilización puede dar lugar a infecciones y contaminación cruzada - No re-esterilizar - Reemplazar cada 48 horas - Utilice una técnica aséptica - Siga las instrucciones del médico - 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 - No doble la aguja	- Soll subkutane Infusion von Medikamenten von einem externen Infusionspumpe oder Spritze zu liefern. - Nur zum einmaligen Gebrauch; Wiederverwendung kann in Infektion führen, und Kreuzkontamination - Nicht Wiedersterilisieren - Alle 48 Stunden ersetzen - Aseptik-Technik verwenden - Ärztliche Anweisungen beachten - 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 - Nadeln nicht biegen	- Destinato a fornire infusione sottocutanea di medicina da una pompa per infusione esterna o una siringa. - Solo monouso; riutilizzo può causare infezioni, e la contaminazione incrociata - Non risterilizzare - Sostituire almeno ogni 48 ore - Utilizzare una tecnica asettica - Seguire le istruzioni del medico - 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 - Non piegare l'ago
	INSERTION	**INSERTION**	**INSERCION**	**EINSETZEN**	**INSERIMENTO**
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 Holräumen 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 asciuga (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 grueso 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

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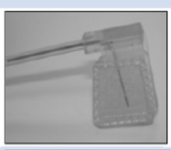
10		Make sure you are not injecting fluid into a blood vessel. To test this, attach a sterile syringe to the end of the infusion tubing. Pull the plunger back gently. If you see any blood in the tubing, take the needle out of the injection site. Throw away the tubing and the needle and start over.	Veillez 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.	Sicherstellen dass kein Blutgefäß angestochen wurde! Dazu mit der Spritze vorsichtig saugen. Falls Blut in der 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. Assicurarsi 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.	Mettre 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
		REMOVAL	**ENLEVEMENT**	**REMOVER**	**ENTFERNEN**	**ESTRAZIONE**
A		Remove dressing	Retirer le ruban adhésif	Remueva el apósito	Klebeband 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 dispositiv 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 zusammendrucken 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 instruc ions	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 Eimalverwendung!	Non riutilizzare
4		Don't use if package is damaged	Ne pas utiliser lorsque l'emballage est endommagé	No utilzar cuando el envase esté dañado	Nicht verwenden wenn Packung beschädigt ist!	Non utilizzare quando l'imballaggio e danneggiato
5	Latex Free	This product is not made with latex	pas fait avec du latex	no hecha de látex	nicht mit Latex	non fatto con il lattice
6	STERILE EO	Sterilized by Ethylene Oxide	Stérilisé par oxyde d'éthylène	Esterilizado por óxido de etileno	Sterilisation mit Äthylen Oxid	Sterilizzato con ossido di etilene
7		Manufacturer	Fabricant	Fabricante	Hersteller	Fabbricante
8	EC REP	EC Representative	Représentant CE	Representante CE	EC Stelle	Rappresentante CE
9	REF	Reference number	Numéro de référence	Número de referencia	Referenz Nummer	Numero di riferimento
10		Manufacturing date	Date de fabrica ion	Fecha de fabricación	Herstellungsdatum	Data di produzione
11	LOT	Batch	Lot	Lote	Los	Lotto
12		Expiration date	Date d'expiration	Fecha de caducidad	Verfallsdatum	Data di scadenza
13		Quantity	Quantité	Cantidad	Menge	Quantità
14	-5°C 40°C	Storage temperature limits	Limites de température de stockage	Límites de temperatura de almacenamiento	Lagertemperatur Grenzen	Limiti de temperatura di stoccaggio
15	SN	Serial number	Numéro de série	Número de serie	Seriennummer	Numero di serie
16	Ø	Diameter	Diamètre	Diámetro	Durchmesser	Diametro
17		Length	Longueur	Longitud	Länge	Lunghezza
18	Rx ONLY	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	Rezeptpflich ig	Utilizzare solo su ordine di un medico
19	≈ XX ml	Approximate priming volume	Approximative volume de remplissage	Volumen aproximado de llenado	Ungefähren füllvolumen	Approssimativo volume di riempimento
20	DEHP Free	Is not made with di(2-ethylhexyl) phthalate (DEHP)	pas fait avec du di(2-ethylhexyl) phthalate (DEHP)	no hecha de di(2-ethylhexyl) phthalate (DEHP)	nicht mit di(2-ethylhexyl) phthalate (DEHP)	non fatto con il di(2-ethylhexyl) phthalate (DEHP)
21	CE	CE Mark	Marquage CE	Marca CE	CE-Kennzeichnung	Marchio CE
22	Non-Pyrogenic	Non-pyrogenic fluid path	Trajet de fluide non-pyrogène	Apirógena fluido ruta	Nicht pyrogen Fluidweg	Apirogena fluido percorso

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

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

REVISION HISTORY

REV	DCR#	CHANGE DESC.	DATE
2.0	03032011-01	To fit new SCIg sets boxes	03/03/11
2.1	05032012-02	Added “Soft-Glide™” mark	05/08/12
3.0-A	12132013-02	Removed (SCIg) ref. added symbols subtitles.	12/13/2013

Notes (Unless Otherwise Specified)
1. 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 AND EXPIRATION DATE FIVE (5) YEARS FROM MFG DATE AND LOT NUMBER PER EMED’S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

Soft-Glide™

Reorder No. / REF *SUB-400*

QTY: **10ea.**

Subcutaneous infusion set (EN)
Dispositif de perfusion sous-cutanée (FR)
Dispositivo de infusión subcutánea (ES)
Subkutanes Infusionsset (DE)
Dispositivo di infusione sottocutanea (IT)

(Polyethylene Lumen)ø2.0 mm OD X ø0.50 mm ID ←→ 91.5 cm [36.0”]

4 Needles / Aiguilles / Agujas / Nadeln / Aghi Ø27G X 6 mm ←→	Priming Volume / Volume de remplissage / Volumen de llenado / Füllvolumen / Volume di riempimento **< 0.8 ml**	Manufacture Date: **DD.MMM.YEAR**	
		Use By: **DD.MMM.YEAR**	
		LOT	**XXXXXXX**

ER-0114_3.0-A

APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN.	Carlos G.	[ON FILE PER DCR]	12/13/2013
ENG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/2013
CHECKED.			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	12/13/2013
Q.A.			

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El Dorado Hills CA, 95762
Tel. 916.932.0071
www.emedtc.com

TITLE: **Artwork, Inner Box Label, SUB-400**

ARTWORK NO. ER-0114 REV 3.0-A

SIZE: A SCALE: 1:1 SHEET 1 OF 1 TEMPLATE NO: MF-0013 REV 1.2

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

Appendix B: Specifications and MSDS

This appendix contains component and device specifications listed in Table B-1 associated with minor modifications made to the predicate and reflected in the EMED SUB-Q subcutaneous tissue infusion sets.

Table B-1

Exhibit	Part No.	Component Description
1	(b)(4) [redacted]	
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		

* NOTE: Due to the large number of intended configurations, provided are representative examples of specification documents for the selected components or assemblies.

The MSDS documents for plasticizers, lubricants, bonding agents, or other materials used in the manufacture of the SUB-Q subcutaneous tissue infusion sets or its components are listed in Table B-2.

Table B-2

Exhibit	Material Description	Material Use
12	(b)(4) [redacted]	
13		
14		

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

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

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(b)(4) Schematic Drawings

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(b)(4) Manufacturing Information

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(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

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

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Kathleen Fitzgerald

510(k) Number K140131

Please list CTS decision code: SE - Substantially Equivalent

☐ Hold (Additional Information or Telephone Hold) Hold Date

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

☐ Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

☐ Add to File
(review staff should follow the instructions and complete the memo/routing sheet at: http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class:	II
Regulation Number:	21CFR 880.5440
Product Code:	FPA
Additional Product Codes:	

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

DOC 4-4

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

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

Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Digitally signed by Richard C. Chapman Date: 2014.04.03 11:02:05 -04'00'
Division Sign-Off	Mary S. Runner S Date: 2014.04.03 11:51:24 -04'00'

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

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K140131/S001

FDA CDRH DMC

MAR 12 2014

Received

3/10/14

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 – SUB-Q Subcutaneous Tissue Infusion Set (K140131)

The following is the additional information requested on 2/26/14 to support the **Special 510(k): Device Modification** (K140131) we have submitted regarding modifications to our SUB-Q Subcutaneous Tissue Infusion Set device.

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

14

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

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.0071 • Fax 916.932.0074 • www.emedtc.com

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3/10/14

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 – SUB-Q Subcutaneous Tissue Infusion Set (K140131)

The following is the additional information requested on 2/26/14 to support the **Special 510(k): Device Modification** (K140131) we have submitted regarding modifications to our SUB-Q Subcutaneous Tissue Infusion Set device.

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

Global Headquarters
1264 Hawks Flight Court, Suite 200 • El Dorado Hills, CA 95762 USA • Tel 916.932.6071 • Fax 916.932.6074 • www.emedtc.com

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

K140131 Additional Information Request Response (3/10/14)

(b)(4) Deficiencies

[redacted]

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

Appendix A: Indications for Use Form

This appendix contains the completed FORM FDA 3881, Indications for Use for the SUB-Q Subcutaneous Tissue Infusion Set.

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

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

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)*
K140131

Device Name
SUB-Q Subcutaneous Tissue Infuset Set

Indications for Use *(Describe)*
SUB-Q Subcutaneous Tissue Infusion Set is intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe.

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)*

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

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

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

Appendix B: Instructions for Use and Labeling

This appendix contains the following:

- Exhibit 1: ER-0064, SUB-400 pouch artwork (representative example)
- Exhibit 2: AS-0010003, SUB-Q IFU

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

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

REVISION HISTORY			
REV.	DCN#	CHANGE DESC.	DATE
1.2	-	INITIAL RELEASE	07/29/10
2.0	05032012-01	ADDED SOFT-GLIDE AND NEW SYMBOLS	05/04/12
2.1	05152012-01	Changed MFG for: & added Assy. In Mex.	05/15/12
3.0-A	12132013-02	Removed (SCIg) and Added subtitles to symbols.	12/13/13
3.0-B	03052014-01	(b)(4) [redacted]	03/05/14

Peel Down

Soft-Glide™

Reorder No. / REF SUB-400

Subcutaneous infusion set (EN)
Dispositif de perfusion sous-cutanée (FR)
Dispositivo de infusión subcutánea (ES)
Subkutanes Infusionsset (DE)
Dispositivo di infusione sottocutanea (IT)

Ø2.0 mm OD 0.5 mm ID ⟷ 91.5 cm [36"]

QTY: 1 ea.	4 Needles / Aiguilles / Agujas / Nadeln / Aghi	Priming Volume / Volume de remplissage / Volumen de llenado / Füllvolumen / Volume di riempimento
	Ø27Ga. ⟷ 6 mm	< 0.8 ml

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

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

STERILE EO (Non-Pyrogenic)

This product is not made with natural rubber latex.

CE 0459

-5°C 40°C Storage temperature limits.

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

Manufacture Date: DD.MMM.YEAR

Use By: DD.MMM.YEAR

LOT XXXXXXX

INSTRUCTIONS FOR USE:
1. Connect Female Luer to source of infusion.
2. Prime infusion set
3. Use each wing to hold set and insert each needle into the skin.
4. Replace per CDC guidelines

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
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

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ER-0064_3.0-B

Notes (Unless Otherwise Specified)
1. COLOR: ARTWORK TO BE PRINTED IN BLUE PMS 285.
2. PRINT ARTWORK ON TYVEK SIDE OF POUCH CENTER HORIZONTAL.
3. POUCH SIZE: 6" X 10"
4. PRINT MANUFACTURE DATE, EXPIRATION DATE 5 YEARS FROM MFG DATE AND LOT NUMBER PER EMED'S SPECIFICATIONS, (SAMPLE 01. JAN. 2012)

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APPROVALS:	NAME:	SIGNATURE:	DATE:
DRAWN.	Carlos G.	[ON FILE PER DCR]	03/05/2014
CHECKED			
MFG APPR.	Carlos G.	[ON FILE PER DCR]	03/05/2014
ENG APPR.	Carlos G.	[ON FILE PER DCR]	03/05/2014
Q.A			

EMED Technologies Corporation
1264 Hawks Flight Court Suite 200
El Dorado Hills CA 95762
Tel. 916.932.0071

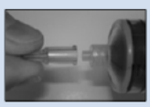
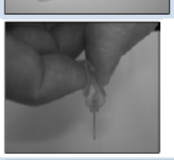
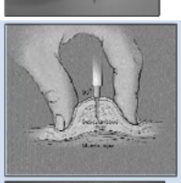
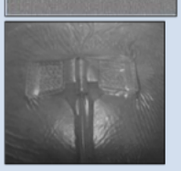
TITLE. Pouch, Artwork label, SUB-400 REV. 3.0-B
ARTWORK No. ER-0064
SIZE: A SCALE: 1:1 SHEET 1 OF 1 TEMPLATE NO. MF-0022 REV 1.3

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

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

EMED Technologies Corporation

SUB-Q set instructions for use

PICTURES	ENGLISH	FRENCH	SPANISH	GERMAN	ITALIAN
WARNING:	- Intended to provide subcutaneous infusion of medicine from an external infusion pump or syringe. - Single use only; reuse can result in infection, and cross contamination - Do not re-sterilize - Replace at least every 48 hours - Use aseptic technique - Follow pharmacy / physician instructions - If fluid source is disconnected during the below steps, stop the process and place a sterile non-vented cap on syringe and set - Do not bend needle - **U.S. Federal Law restricts this device to sale by or on order of a physician**	- Destiné à fournir perfusion sous-cutanée de la médecine d'une pompe à perfusion externe ou d'une seringue. - Usage unique, la réutilisation peut entraîner une infection, et la contamination croisée - Ne pas restériliser - Remplacer au moins toutes les 48 heures - Utiliser une technique aseptique - Suivez les instructions du médecin - 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 - Ne pas plier l'aiguille	- Pensado para proporcionar una infusión subcutánea de la medicina de una bomba de infusión externa o una jeringa - Un solo uso, la reutilización puede dar lugar a infecciones y contaminación cruzada - No re-esterilizar - Reemplazar cada 48 horas - Utilice una técnica aséptica - Siga las instrucciones del médico - 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 - No doble la aguja	- Soll subkutane Infusion von Medikamenten von einem externen Infusionspumpe oder Spritze zu liefern. - Nur zum einmaligen Gebrauch; Wiederverwendung kann in Infektion führen, und Kreuzkontamination - Nicht Wiedersterilisieren - Alle 48 Stunden ersetzen - Aseptik-Technik verwenden - Ärztliche Anweisungen beachten - 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 - Nadeln nicht biegen	- Destinato a fornire infusione sottocutanea di medicina da una pompa per infusione esterna o una siringa. - Solo monouso; riutilizzo può causare infezioni, e la contaminazione incrociata - Non risterilizzare - Sostituire almeno ogni 48 ore - Utilizzare una tecnica asettica - Seguire le istruzioni del medico - 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 - Non piegare l'ago
	INSERTION	**INSERTION**	**INSERCION**	**EINSETZEN**	**INSERIMENTO**
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 Holräumen 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 asciuga (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 grueso 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

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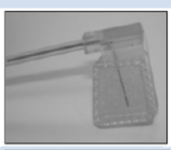
10		Make sure you are not injecting fluid into a blood vessel. To test this, attach a sterile syringe to the end of the infusion tubing. Pull the plunger back gently. If you see any blood in the tubing, take the needle out of the injection site. Throw away the tubing and the needle and start over.	Veillez 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.	Sicherstellen dass kein Blutgefäß angestochen wurde! Dazu mit der Spritze vorsichtig saugen. Falls Blut in der 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. Assicurarsi 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.	Mettre 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
		REMOVAL	**ENLEVEMENT**	**REMOVER**	**ENTFERNEN**	**ESTRAZIONE**
A		Remove dressing	Retirer le ruban adhésif	Remueva el apósito	Klebeband 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 dispositiv 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 zusammendrucken 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 instruc ions	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 Eimalverwendung!	Non riutilizzare
4		Don't use if package is damaged	Ne pas utiliser lorsque l'emballage est endommagé	No utilzar cuando el envase esté dañado	Nicht verwenden wenn Packung beschädigt ist!	Non utilizzare quando l'imballaggio e danneggiato
5	STERILE EO	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 REP	EC Representative	Représentant CE	Representante CE	EC Stelle	Rappresentante CE
8	REF	Reference number	Numéro de référence	Número de referencia	Referenz Nummer	Numero di riferimento
9		Manufacturing date	Date de fabrica ion	Fecha de fabricación	Herstellungsdatum	Data di produzione
10	LOT	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	-5°C 40°C	Storage temperature limits	Limites de température de stockage	Límites de temperatura de almacenamiento	Lagertemperatur Grenzen	Limiti de temperatura di stoccaggio
14	SN	Serial number	Numéro de série	Número de serie	Seriennummer	Numero di serie
15	Ø	Diameter	Diamètre	Diámetro	Durchmesser	Diametro
16		Length	Longueur	Longitud	Länge	Lunghezza
17	Rx ONLY	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	Rezeptpflich ig	Utilizzare solo su ordine di un medico
18	≈ XX ml	Approximate priming volume	Approximative volume de remplissage	Volumen aproximado de llenado	Ungefähren füllvolumen	Approssimativo volume di riempimento
19	CE	CE Mark	Marquage CE	Marca CE	CE-Kennzeichnung	Marchio CE
20	Non-Pyrogenic	Non-pyrogenic fluid path	Trajet de fluide non-pyrogène	Apirógena fluido ruta	Nicht pyrogen Fluidweg	Apirogena fluido percorso

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Appendix C: Design Control Activities Summary

This appendix contains the revised Section 12, Risk Analysis and Design Controls for the SUB-Q Subcutaneous Tissue Infusion Set.

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Section 12: Risk Analysis and Design Controls

Impact of the minor modifications made to the predicate described in section 10, Device Description and Substantial Equivalence, were carefully evaluated to assess and mitigate potential safety and effectiveness concerns regarding the device. Risk Analysis of SUB-Q Tissue Infusion Sets with the modifications was performed per EMED internal procedures in line with FMEA analysis techniques described in ISO 14971.

The minor modifications made to the predicate relating to changes to physical dimensions such as length, inner diameter, and outer diameter and addition of non-fluid path contacting accessories, were evaluated and found to present insignificant additional risk to the user when compared to the predicate.

These minor modifications presented insignificant impact to manufacturing and assembly as well, in that critical assembly steps (assembly of tubing and connectors, validated UV-bonding, packaging, validated ETO sterilization) are the same as used in the assembly of the predicate and will remain unchanged.

The same Final Product Test methods and acceptance criteria applied to the predicate will be applied to each finished lot of the EMED SUB-Q products prior to commercial release. This ensures that the finished product incorporating the minor modifications will provide the same performance as the predicate. Finished Product Testing includes evaluation of leakage, occlusion, and visual defects from a random sample of production units. Sample sizes and acceptance criteria for each test attribute are (b)(4) [redacted] (b)(4) [redacted] and are based on total lot size and criticality of the attribute.

Introduction of biconnectors and triconnectors into the SUB-Q design did not introduce increased risk due to the materials and bonding agents being equivalent to those used in the predicate, and therefore does not affect the general technical characteristics of the product or its intended use. As stated above, the same UV- bonding, assembly, packaging, sterilization, and Finished Product testing processes associated with the predicate will be applied to the EMED SUB-Q Tissue Infusion sets, thus ensuring the minor modification of adding the biconnector and triconnectors to the design results in devices of the same quality and performance as the predicate. The materials and design of the biconnectors and triconnectors are further discussed in Section 10, Device Description and Substantial Equivalence.

The addition of Dow Corning 360 medical grade liquid silicone was established as a safe and effective needle lubricant used throughout industry, as supported by material information sheets and material safety data (see Appendix B). Development tests were performed that confirmed production-equivalent application of the silicone lubricant consistently provided decreased penetration force for needle insertion. With the information provided by the supplier and that found in published and public literature,

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sufficient evidence was available to establish that the addition of Dow Corning 360 silicone lubricant to the predicate design is a minor modification that performs as intended and poses insignificant risk to the user as compared to the predicate.

Table 12-1 summarizes risk analysis, risk mitigation, and design verification activities performed to support the conclusion of limited impact resulting from the changes to the SUB-Q design, assembly process, and finished products. Information provided in this DCAS table is intended supplement and support information already presented in this discussion.

12-1

New Item(s)	Risk/ Potential Harms	Possible Causes	Verification Activity	Acceptance Criteria	Results

(b)(4)

[redacted]

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New Item(s)	Risk/ Potential Harms	Possible Causes	Verification Activity	Acceptance Criteria	Results
(b)(4) [redacted]					

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New Item(s)	Risk/ Potential Harms	Possible Causes	Verification Activity	Acceptance Criteria	Results
(b)(4) [redacted]					

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Table 12-2

Modification	Rationale
(b)(4) [redacted]	

Conclusion

Design control and risk management activities were performed to evaluate the minor modifications to the predicate, to establish the residual risk related to the modifications, and perform any necessary actions to decrease residual risk to acceptable levels. These actions resulted in a design that is substantially equivalent to the commercially available predicate device in terms of function, safety, performance, intended use, technology/principles and mechanical properties. Any differences between the EMED SUB-Q Tissue Infusion Set and the predicate do not raise any new issues of safety or effectiveness.

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