December 14, 2018

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

Re: K173783
Trade/Device Name: SCIg60 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP
Dated: December 12, 2017
Received: December 13, 2017

Dear Peter 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn C. Dorgan -S

Digitally signed by Carolyn C. Dorgan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001800814, cn=Carolyn C. Dorgan -S
Date: 2018.12.14 15:18:30 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173783

Device Name
SCIg60 Infusion System

Indications for Use *(Describe)*
The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring), Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) with the BD 60ml syringe (model no. 309653)

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K173783 510(K) SUMMARY

Preparation Date:	December 14, 2018
Manufacturer's Name:	EMED Technologies Corporation 1264 Hawks Flight Ct, El Dorado Hills, CA 95762
Corresponding Official:	Peter Kollings Director Regulatory Affairs and Quality Assurance
Telephone Number:	916-932-0071
Fax Number:	916-932-0074
E-mail Address:	pkollings@emedtc.vom
Trade Name:	SCIg60 Infusion System
Common or Usual Name:	Immunoglobulin G(Igg) Infusion System
Regulation Name:	Infusion pump
Regulation Number:	21 CFR 880.5725
Product Code:	PKP
Device Class:	Class II
Primary Predicate Device:	K161906, SCIg60 Infuser

Device Description

The EMED SCIg60 Infusion System consists of :

- SCIg60 Infuser
- fixed-rate Infuset flow control extension set
- VersaRate variable-rate flow regulator
- SUB-Q patient administration set

The SCIg60 Infuser must be used with the BD 60 ml syringe (model no. 309653). The Infuset flow control extension sets, VersaRate flow regulator, and SUB-Q patient administration sets are also manufactured by EMED Technologies.

The SCIg60 Infuser is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The EMED SCIg60 Infuser uses a spring as a source of pressure for the subcutaneous infusion of indicated human plasma-derived immunoglobulin solutions.

The Infuset flow control extension sets are assembled from standard luer lock components and specified lengths of PVC microbore tubing. The length and diameter of the tubing results in predetermined flow rates when used with the SCIg60 Infuser, and include slide-clamps for stopping the flow of fluid. The SCIg60 Infuser user manual includes information to guide users in the selection of Infuset flow control extension sets and SUB-Q patient administration sets users to achieve the desired infusion rates.

The change proposed in this 510(k) includes the addition of the VersaRate flow regulator. The VersaRate flow regulator consists of a barrel-type regulator component, medium-density PVC tubing, and rigid PVC standard luer lock connectors. Snap-fit design elements of the regulator halves hold the gasket in place and allow the VersaRate to withstand fluid pressures up to 18 psi. The rotation of the flow dial of the flow regulator component alters internal fluid path dimensions,

thereby changing the resulting flow rate. This capability allows one VersaRate to provide the flow control of multiple individual Infuset flow control sets. SCIg60 Infusion System should be used in accordance with its directions for use.

Indications for Use

The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring), Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) with the BD 60ml syringe (model no. 309653)

The device is prescription only.

Intended Use

To pump fluids from a reservoir into an adult or pediatric patients (2 years and older) in a controlled manner in a home or hospital environment.

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate Device** SCIg60 Infuser K161906	**Subject Device** SCIg60 Infusion System K173783
Indications for Use	The SCIg60 Infusion System is intended for use in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring), Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) with the BD 60 ml syringe (model no. 309653).	The SCIg60 Infusion System is intended for us in the home or hospital environment for the subcutaneous infusion of Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid (manufactured by CSL Behring), Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) with the BD 60ml syringe (model no. 309653)
Prescription Only or Over the Counter	Prescription Only	Prescription Only
Intended Population	adult or pediatric patients (2 years and older)	adult or pediatric patients (2 years and older)
Environment of Use	Home or hospital	Home or hospital

Discussions of differences in Indications for Use statement

The indications for use statement for the subject device is identical to the predicate device.

Discussions of differences in intended population

The intended population for the subject device is identical to the predicate device.

Discussions of differences in environment of use

The environment of use for the subject device is identical to the predicate device.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	**Predicate Device** SCIg60 Infuser K161906	**Subject Device** SCIg60 Infusion System K173783	**Comments**
Infuser Material(s)	PPE Resin Delrin Stainless Steel	PPE Resin Delrin Stainless Steel	Same
Infuser Weight	1 lb	1 lb	Same
Infuser Dimensions (L x H x D)	10.2” x 2.6” x 2.6”	10.2” x 2.6” x 2.6”	Same
Syringe/Fluid Container	BD 60ml Syringe (model no. 309653)	BD 60ml Syringe (model no. 309653)	Same
Principle of Action	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.	Spring force generated by user infuses liquid through flow regulating accessories; no batteries/electrical power.	Same
Pressure Source	Spring	Spring	Same
Principle of Flow Control	Flow rate result of internal dimensions of flow control set.	Flow rate result of internal dimensions of flow control set.	Same
Materials	PVC	PVC (Infuset) PVC, Polycarbonate, Styrene-ethylene-butylene (VersaRate)	Same/See Comment #1
Flow Controller Residual Volume	0.10 – 0.20 ml (Infuset)	0.10 – 0.20 ml (Infuset) 0.20 ml (VersaRate)	See Comment #2
Flow Controller Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Maximum Operating Pressure (psi)	16.8	16.8	Same
Average Operating Pressure (psi)	14.4	14.4	Same
Total Flow Rate Range (ml/hr)	11 – 145	9 – 145	See Comment #3
Flow Rate Accuracy (%)	+/- 15 (Infuset only)	+/- 15 (Infuset only) Up to +/- 37 (VersaRate, Positions ½ - 1) Up to +/- 26 (VersaRate, Positions 2-3) Up to +/- 15 (VersaRate, Positions 4-6)	See Comment #4
Verticle Sensitivty at +12” At -12”	Up to +6% from target flow rate Up to -4% from target flow rate	Up to +6% from target flow rate Up to -4% from target flow rate	Same

Discussions of differences in technological characteristics

Comment 1
The patient-contacting and fluid path materials of the subject SCIg60 Infuser and Infuset flow control accessory are identical to that of the predicate, K161906. The manufacturing, processing, and packaging processes of the subject SCIg60 Infuser and Infuset flow control accessory are identical to that of the predicate, K161906.

The patient contacting and fluid path materials of the subject VersaRate flow control accessory are identical to the currently marketed VersaRate Controller (K123729). The contact type and duration is similar from a biocompatibility perspective. The subject device is indicated for subcutaneous administration whereas the VersaRate controller (K123729) is indicated for intravenous. However, there are no additional biocompatibility endpoints that need to be evaluation for this change of intended use. The previous determination that the biocompatibility endpoints have been verified to meet the intravenous route of administration per K123729 can be leveraged to determine that the addition of this component to the subject device does not raise different questions of safety and effectiveness.

Comment 2
VersaRate controller has up to 0.10mL higher residual volume that the predicate device. However, the difference is not clinically significant. This does not raise different questions of safety or effectiveness.

Comment 3
The total flow rates of the subject device are within the range of the predicate device. In addition, the total flow rates that are achieved with the subject device when used as indicated (manufacturer recommended flow rate limits) are substantially equivalent to those of the predicate.

Comment 4
Flow rate accuracy of the SCIg60 Infusion System employing the VersaRate variable rate flow control accessory is more variable at low flow rates than that of the predicate. This increased variation, expressed as a % of target, at low VersaRate positions (that equate to lower flow rates) is expected in that a small difference between measured flow rate and target flow rate results in a large % difference. Given that the VersaRate provides a similar variability in terms of ml/hr across its positions, flow rate variation in terms of % of target would be expected to be much smaller for higher VersaRate positions and the resulting higher target flow rates.

As with the predicate, instructions for use and labeling for the subject SCIg60 Infusion System employing the VersaRate variable flow control accessory include only those combinations of VersaRate position and SUB-Q sets that provide flow rate performance in line with indicated immunoglobulin manufacturer recommendations. Combinations that allow for flow rates that exceed manufacturer recommendations taking into account system accuracy and vertical sensitivity are excluded.

Because only those VersaRate position and SUB-Q combinations that meet label requirements for administration of each of the indicated immunoglobulin solutions are presented in user instructions, any differences in flow rate accuracy provided by the VersaRate or Infuset flow control devices are well controlled, do not adversely impact users, and do not raise different questions of safety or effectiveness of the system when it is used as intended

Performance Testing

The following bench testing was performed and reviewed to support the substantial equivalence of the subject device:

- Validation of simulated test fluids
- Infusion flow rate testing with SCIg60 Infusion System and indicated human plasma-derived immunoglobulin solutions*

- Influence of elevation on flow rate for indicated human plasma-derived immunoglobulin solutions
- Infusion flow rate testing with combinations of SCIg60 Infuser, VersaRate flow regulator positions and SUB-Q patient administration sets, and Infuset flow control sets and SUB-Q patient administration sets was performed with simulated test fluid for the indicated human plasma-derived immunoglobulin solutions. Additional performance and flow rate testing was conducted per:
    - ISO 85368:2015 Infusion equipment for medical use – Part 8: Infusion sets for single use with pressure infusion apparatus
- Human factors validation of the SCIg60 Infusion System, including additional evaluation of critical tasks associated with introduction of the VersaRate Flow rate controller as well as with the currently indicated immunoglobulin solutions. The testing was conducted per:
    - Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices, 2016 (https://www.fda.gov/downloads/MedicalDevices/.../UCM259760.pdf)
    - ANSI/AAMI HE75:2009 – Human Factors engineering – Design of medical devices
- Compatibility of human plasma-based immunoglobulin solutions with the SCIg60 Infusion System, including the VersaRate flow control accessory, related to adverse impact to either the SCIg60 Infusion System or the indicated fluids.
- Particulate testing per USP <788>

* The SCIg60 Infusion System includes directions for the selection of Infuset flow control extension sets and SUB-Q set combinations, or VersaRate flow controller positions and SUB-Q set combinations, in order to achieve desired infusion rates for each of the indicated human plasmaderived immunoglobulin solutions.

Only those combinations that provide flow rate performance in line with indicated immunoglobulin manufacturer recommendations after taking into account total system accuracy and vertical sensitivity are included. This strategy is identical to that employed in K161906 for presenting only Infuset and SUB-Q set combinations that meet label requirements for administration of each of the indicated immunoglobulin solutions.
A safety assurance case was provided for the SCIg60 Infusion System, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209337.pdf) .

The stated goal of the safety assurance case is:

- The SCIg60 Infusion System is adequately safe for its intended use.

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments covered the following attributes:

(1) Device is adequatelt defined (as a contet for the assurance case)
(2) Device design is adequately verified and validated
(3) Device associated risks are completely identified and adequately mitigated
(4) Device is adequately reliable to ensure safety over device use life

The following specific evidence was included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices:

- SCIg60 Infuser Product Requirements Matrix
- SCIg60 Infusion Pump Design Verification Report
- SCIg60 Infusion Pump Design Validation Report

In addition, the safety assurance case has been updated to include unique hazards associated with use of the VersaRate flow control accessory as part of the SCIg60 Infusion System, such as those related to selection of flow control positions to achieve target flow rates, and acceptable use and performance of the VersaRate “Off” function.

Clinical Tests

Not Applicable

Conclusions

The differences between the predicate and the subject device do not raise any different questions of safety or effectiveness. The SCIg60 Infusion System is substantially equivalent to the SCIg60 Infuser cleared under K161906 with respect to the indications for use, target populations, treatment method, and technological characteristics.