EMED Technologies Corporation
Olena Whalen
QA/RA/CA Manager
1262 Hawks Flight Court
Suite 200
El Dorado Hills, California 95762

October 13, 2022

Re: K222087
Trade/Device Name: SCIg60 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP
Dated: June 2, 2022
Received: July 15, 2022

Dear Olena Whalen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Courtney H. Lias, Ph.D.
Office Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222087

Device Name
SCIg60 Infusion System

Indications for Use *(Describe)*
The SCIg60 Infusion System is intended for the subcutaneous infusion of the following immunoglobulin liquid medications:
• Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring),
• Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Takeda Pharmaceutical Company, formerly Baxalta),
• Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Takeda Pharmaceutical Company, formerly Baxalta)
• Gamunex-C Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.),
• Gammaked Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.)
• Xembify Immune Globulin Subcutaneous (Human), 20% (manufactured by Grifols Therapeutics, Inc.), and
• Cutaquig Immune Globulin Subcutaneous (Human), 16.5% (manufactured by Octapharma AG)
with the BD 50 ml syringe (model no. 309653) in the home or hospital environment.

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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510(k) Summary

K-number: K222087

Date Prepared: October 11, 2022

I. SUBMITTER

EMED Technologies Corporation
1262 Hawks Flight Ct
El Dorado Hills, CA 95762

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II. DEVICE

Trade Name: SCIg60 Infusion System
Common or Usual Name: Infusion Pump
Classification Name: Infusion pump
Regulation Number: 21 CFR §880.5725
Product Code: PKP (Immunoglobulin G (IgG) infusion system)

III. PREDICATE DEVICES

Primary Predicate Device:
K161906, SCIg60 Infusion System (Product Code – PKP)

IV. DEVICE DESCRIPTION

The EMED SCIg60 Infusion System consists of the SCIg60 Infuser Pump, a flow rate controller (Infuset fixed rate flow control extension set, VersaRate variable flow rate controller, or VersaRate Plus variable flow rate controller), and can be used with commercially available SUB-Q administration sets that utilize a standard Luer Lock style connector. The SCIg60 Infuser Pump must be used with the BD 50 mL syringe (model no. 309653 manufactured by Becton Dickinson (BD)), which was formerly labeled as a 60 mL syringe.

The SCIg60 Infuser pump is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The SCIg60 Infuser Pump uses a spring as a source of energy to provide pressure for the subcutaneous infusion of the indicated human plasma-derived immunoglobulin solutions. The SCIg60 Infuser Pump is provided with a carrying case and User Manual.

The Infuset flow rate controller is an individually packaged, sterile, single use device. It is assembled from standard Luer components and specified lengths of PVC microbore tubing. The length and diameter of the tubing results in fixed flow rates when used with the SCIg60 Infuser Pump, and include side-clamps for stopping the flow of fluid. The

SCIg60 Infusion System User Manual includes information to guide users in the selection of Infuset flow rate controller and SUB-Q patient administration sets to achieve the desired infusion rates.

The VersaRate or VersaRate Plus variable flow rate controllers are individually packaged, sterile, single use devices. They may be used with the SCIg60 Infuser Pump to provide convenient control of the flow rate without having to select specific Infuset flow rate controller. The barrel-shaped dial (VersaRate) or flat dial (VersaRate Plus) can be adjusted by turning a barrel or dial in order to set an appropriate flow rate of immune globulin solution, or stop the fluid flow entirely. The SCIg60 Infusion System User Manual includes information to guide users in the selection of VersaRate (or VersaRate Plus) settings and SUB-Q patient administration sets to achieve the desired infusion rates.

Intended Use/Indications for Use:
The SCIg60 Infusion System is intended for the subcutaneous infusion of the following immunoglobulin liquid medications:

- Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring),
- Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta),
- Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta)
- Gamunex-C Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.),
- Gammaked Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.),
- Xembify Immune Globulin Subcutaneous (Human), 20% (manufactured by Grifols Therapeutics, Inc.), and
- Cutaquig Immune Globulin Subcutaneous (Human), 16.5% (manufactured by Octapharma AG)

with the BD 50 ml syringe (model no. 309653) in the home or hospital environment.

V. COMPARISON WITH PREDICATE DEVICES

The proposed indications for use of the SCIg60 Infusion System are identical to that of the predicates with the exception that infusion of Gamunex-C, Gammaked, Xembify, and Cutaquig are included. Please note that Gamunex-C and Gammaked are the same drug, with the exception of the private label name used by Gammaked.

Table 6-1: Comparison of Technological Characteristics with Predicates

Parameter	Predicate (K161906)	EMED SCIg60 Infusion System with expanded biologics	Comparison
Intended Use	To pump fluids from a reservoir into a patient in a controlled manner	To pump fluids from a reservoir into a patient in a controlled manner	SAME
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	The SCIg60 Infusion System is intended for the subcutaneous infusion of the following immunoglobulin liquid medications: • Hizentra, Immune Globulin Subcutaneous (Human) 20% (manufactured by CSL Behring),	Added 4 Ig biologics

	Infusion (Human), 10% (manufactured by Baxalta), Cuvitru Immune Globulin Infusion (Human), 20% (manufactured by Baxalta) with the BD 60 ml syringe (model no. 309653)	• Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta), • Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta) • Gamunex-C Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.), • Gammaked Immune Globulin Subcutaneous (Human), 10% (manufactured by Grifols Therapeutics, Inc.), • Xembify Immune Globulin Subcutaneous (Human), 20% (manufactured by Grifols Therapeutics, Inc.), and • Cutaquig Immune Globulin Subcutaneous (Human), 16.5% (manufactured by Octapharma AG) with the BD 50 ml syringe (model no. 309653) in the home or hospital environment.	
Prescription or Over the Counter	Prescription	Prescription	SAME
Intended Population	Adult and pediatric	Adult and pediatric	SAME
Environment of Use	Hospital or home	Hospital or home	SAME
SCIg60 INFUSER:			
Infuser Material(s)	Noryl GFNI LNP Lubricomp ZFL31XXC Delrin Stainless Steel	Noryl GFNI LNP Lubricomp ZFL31XXC Delrin Stainless Steel	SAME
Infuser Weight	1 lb.	1 lb.	SAME
Infuser Dimensions	10.2” x 2.6” x 2.6”	10.2” x 2.6” x 2.6”	SAME
Syringe/Fluid Container	BD 50 ml syringe, model number 309653 *	BD 50 ml syringe, model number 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
FLOW CONTROLLERS:			
Fixed Flow Controllers Principle of Action	Infuset - Fixed flow rate due to fixed length and inner-diameter of tubing	Infuset - Fixed flow rate due to fixed length and inner-diameter of tubing	SAME
Variable Flow Controllers Principle of Action	VersaRate - Variable flow rate using dial that alters fluid path dimensions	VersaRate Plus - Variable flow rate using dial that alters fluid path dimensions	SAME
Flow Settings	VersaRate – 6 settings plus off	VersaRate Plus – 12 settings plus off	SIMILAR

Flow Rate Range	VersaRate: - 13-285 ml/h (saline w/o SCIg60 System) - 9-156 ml/h (Igg with SCIg60 System)	VersaRate Plus: - 20-356 ml/h (saline w/o SCIg60 System) - 9-271 ml/h (Igg with SCIg60 System)	SIMILAR
Fluid Path Materials	Infuset: PVC VersaRate: Polycarbonate, styrene-ethylene-butylene	Infuset: PVC VersaRate: Polycarbonate, styrene-ethylene-butylene VersaRate Plus: Polycarbonate, Polyoxymethylene (Delrin)	SIMILAR
Flow Controller Residual Volume	0.10-0.25 ml	0.10-0.25 ml	SAME
Flow Controller Sterilization	Ethylene Oxide, SAL of 10^{-6}, cycle 104	Ethylene Oxide, SAL of 10^{-6}, cycle 104	SAME

***** Note that the syringe used with the SCIg60 infusion system is a BD syringe, model 309653. This syringe was formerly labeled by BD as a 60 ml syringe, but has since been re-labeled as a 50 ml syringe. It is the same product (without the 60 ml barrel markings), and has the same model number.

VI. INIDCATIONS FOR USE COMPARISON

The key difference between the subject device and the predicates is the expanded indications of use to include additional brands and concentrations of the same type of biologic product, namely human plasma-derived immunoglobulin G (IgG) solutions.

To determine the degree of similarity between the immunoglobulin solutions, and therefore the likelihood of adverse interaction with the SCIg60 Infusion System, information and product attributes of the indicated immunoglobulin solutions were obtained from their Prescribing Information inserts, published literature, and through testing performed at EMED and outside laboratories. EMED has assessed the differences between the specified biologics to determine if they raise any new issues of safety or effectiveness. It was determined that the protein concentration, pH, osmolarity, viscosity, and density are similar between all the biologics, and any minor differences do not alter the intended therapeutic effect of the SCIg60 Infusion System when the system is used as labeled.

The SCIg60 Infusion System has also been qualified for infusion of the additional proposed immunoglobulin solutions. Performance tests, labeling, and risk management activities qualify the SCIg60 Infusion System for use with Gamunex-C, Gammaked, Xembify and Cutaquig, and satisfactorily mitigate any risks associated with the addition of these specific immunoglobulin solutions.

VII. TECHNOLOGICAL COMPARISON

The overall principle of action for the SCIg60 Infusion System consists of a constant force source acting upon a syringe filled with fluid, with the flow rate of that fluid being regulated by PVC tubing with fixed fluid path dimensions (i.e., tubing length and inner diameter) in the case of Infuset, or by the change in fluid path upon adjusting the flow dial of the VersaRate and VersaRate Plus variable flow rate controllers.

The SCIg60 Infuser Pump, Infuset flow control extension sets, and VersaRate flow controller are identical to those presented in K161906. The VersaRate Plus^{TM} is identical

to the VersaRate™, except for the new flow rate regulator module and diverter/gasket material.

SCIG60 INFUSER:
The material(s), weight, dimensions, syringe/fluid container and principle of action of the proposed infuser compared to the predicate described in K161906 are identical.

Static Operating Pressure: The design and manufacture of the SCIg60 that is the subject of this premarket clearance submission and that found in K161906 is identical, and therefore the pressure provided by this device is also identical.

FLOW CONTROLLERS:
The materials, dimensions, design, principles of action, manufacturing, and sterilization (of single use disposable accessories) of the subject device and the device described in K161906 are similar. Both VersaRate Plus™ and VersaRate™ are intended for the same use and the two devices have similar biocompatibility profiles.

Principle of Action
The principle of action of the VersaRate Plus and VersaRate are the same: rotating the dial alters fluid path dimensions internal to the flow regulator component that is the key functional element of these variable flow controllers. EMED has generated a detailed Risk Management Matrix for both devices, and the mitigated risks are similar. When used according to EMED's IFUs and the SCIg60 User Manual, both devices have been determined to be safe and effective for their intended use.

Dial settings
VersaRate has 7 positions: off, full open, and 5 intermediate positions. VersaRate Plus has 13 positions: off, full open, and 11 intermediate positions. The additional positions of the VersaRate Plus enable the VersaRate Plus to be used with more needle sets, compared to the VersaRate. As each needle set (and connected tubing) represents a different flow resistance, the user must consult tables of flow rates for the different needle sets (including multiple needles) that are provided in the SCIg60 User Manual. Tables are provided for the Infuset, VersaRate, and VersaRate Plus. Therefore, the specific dial position (VersaRate or VersaRate Plus) is selected to achieve a specific flow rate through a specific needle set depending on which flow controller is used.

Flow rate ranges
When tested with saline with gravity feed, 80cm height, during bench testing, the VersaRate flow rates range from 13-285 ml/h (not including the full-open position), while the VersaRate Plus flow rates range from 20-356 ml/h (not including the full-open position). However, EMED has done substantial testing of the VersaRate Plus to ensure that it can provide equivalent flow rates to the VersaRate for various needle sets and biologics. The flow rate for both VersaRate and VersaRate Plus are comparable when tested as a system (with the SCIg60 Infuser pump, biologic and a needle set) - 9-156 ml/h (VersaRate) and 9-271 ml/h (VersaRate Plus). The SCIg60 User Manual specifies flow controller settings to achieve the required flow rate with a given drug and needle set. All flow rates provided in the SCIg60 User Manual are within the drug PI limits.

Materials

The VersaRate Plus™ flow rate controller has all the same materials (except the diverter/gasket) as the original VersaRate™. Luer lock connectors are made of the exact same material (Rigid PVC Nan-Ya 3MTA002GXX-001) and utilize the same molding process and supplied by the same source. Tubing is the same material (PVC 7477G-015), and extrusion process is used for both product configurations. Protective Luer caps are the exact same components for both product configurations. Assembly process is equivalent for both product configurations; assembled by the same supplier. The same packaging materials and sterilization process are used for both product configurations. Based on EMED analysis and supporting engineering reports, the VersaRate Plus™ does not introduce any new risks or substantially modify risks of the original VersaRate™ flow controller. VersaRate Plus™ was tested to demonstrate compliance with the chemical requirements in accordance with ISO 8536-9:2015.

Sterility and Manufacture/Processing

No changes to the sterilization method, cycle, Sterility Assurance Level (SAL) or the pyrogenicity test method have been made.

EMED sterilization validation per ISO 11135:2014 demonstrated that the sterilization process and equipment used for sterilization of EMED flow controllers continues to be reliable, consistent, and capable of sterilizing EMED products at a minimum SAL of 10^{-6} using cycle 104 and 100% Ethylene Oxide. The residual results for EO and ECH were evaluated per ISO 10993-7:2008/Amd 1:2019 and confirmed to not exceed the allowable limits for EO and ECH residues after sterilization.

SCIG60 SYSTEM:

Flow Rate Performance: Testing to determine flow rates provided by the SCIg60 Infusion System when used with the additional indicated immunoglobulin solutions was performed using the indicated BD 50ml syringe and a variety of combinations of the Infuset Flow Control Extension Sets, VersaRate and VersaRate Plus flow controllers, and EMED SUB-Q administration sets. The test strategy employed for the indicated immunoglobulin solutions flow rate performance determination was identical to that used in K161906 to establish flow rate performance of the SCIg60 Infusion System with Hizentra.

The performance of the EMED SCIg60 Infusion System when used with indicated immunoglobulin solutions is equivalent to that of the predicate. Flow rates of infused fluids are dependent on fluid characteristics such as density and viscosity, and therefore minor differences between flow rates established for Hizentra in the predicate and the newly indicated immunoglobulin solutions in the subject device is expected. Specifically, the 10% immunoglobulin solutions (Gamunex-C and Gammaked) and 16.5% immunoglobulin solution (Cutaquig) show a higher flow rate than the 20% solutions (Hizentra, Cuvitru, Xembify) due to their lower viscosity.

EMED fully characterized the flow rates for the proposed immunoglobulin solutions, and they are equivalent to those provided by the SCIg60 Infusion System when used with the Hizentra as found in K161906. Additionally, only those combinations of Infuset,

VersaRate, VersaRate Plus and EMED SUB-Q sets that provide flow rate performance in line with indicated immunoglobulin manufacturer recommendations are included in this assessment, as well as SCIg60 Infusion System labeling and Instructions for Use. Combinations that allow for flow rates that exceed manufacturer recommendations are not provided.

Therefore, any differences in flow rate performance are minor and do not raise new questions of safety or effectiveness of the device when the SCIg60 Infusion System is used as intended.

Package Labeling and User Instructions: Product packaging, labeling, and User Instructions are identical to that of the predicate with the exception that pertinent sections have been updated as necessary to reflect the expansion of indicated uses to include the infusion of Gamunex-C, Gammaked, Xembify, and Cutaquig. Any updates to User Instructions to reflect use of the additional indicated immunoglobulin solutions follow the same format and structure of that of the original User Instructions submitted in K161906.

VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

No clinical study is included in this submission.

Various performance tests were conducted to verify the SCIg60 Infusion System successfully satisfied user needs and product requirements stated in the Patient Information inserts of the new subcutaneously infused immunoglobulin medicines. The data generated by the performance tests demonstrates that the EMED Technologies Corporation SCIg60 Infusion System, including the SCIg60 Infuser Pump, Infuset flow control extension sets, VersaRate and VersaRate Plus flow controllers, used with SUB-Q patient administration sets, is substantially equivalent to the predicate devices and provides infusion rates consistent with the FDA approved human plasma-derived immunoglobulin labeling, when used as directed.