November 28, 2023

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

Re: K230883
Trade/Device Name: VersaPump Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP
Dated: October 27, 2023
Received: October 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director, Infusion Devices
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230883

Device Name
VersaPump Infusion System (FP-0010209)

Indications for Use *(Describe)*
The VersaPump Infusion System is intended for the subcutaneous infusion of indicated fluids for patients in the home or hospital environment when administered by an adult according to the indicated fluid's product labeling and with specified models of subcutaneous infusion sets, flow controllers, and syringes. The system is intended for single patient, multiple use only.

The VersaPump Infusion System is indicated for adult and pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional. The infusion system must be operated by an adult for use with pediatric patients.

The VersaPump Infusion System is indicated for the subcutaneous infusion of:
• Cuvitru Immune Globulin Infusion (Human) 20%, manufactured by Takeda,
• Gammagard Liquid, Immune Globulin Infusion (Human) 10%, manufactured by Takeda,
• Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring,
• Gamunex-C Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics
• Gammaked Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics
• Xembify Immune Globulin Subcutaneous (Human) 20%, manufactured by Grifols Therapeutics, and
• Cutaquig Immune Globulin (Human), 16.5%, manufactured by Octapharma AG.

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.

510(k) Summary

K230883

Date Prepared: November 8, 2023

I. SUBMITTER

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

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II. DEVICE

Trade Name: VersaPump Infusion System
Common or Usual Name: Infusion Pump
Classification Name: Infusion pump (21 CFR §880.5725)
Regulatory Class: II
Product Code: PKP (Immunoglobulin G (IgG) infusion system)

III. PREDICATE DEVICES

K222087, SCIg60 Infusion System (Product Code – PKP)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The VersaPump Infusion System consists of the VersaPump Infuser designed to be used as a system with a flow rate controller (Infuset™ fixed flow rate control infusion set or VersaRate Plus™ variable flow rate control infusion set) and SUB-Q administration sets that utilize a standard Luer lock connector.

The VersaPump Infuser is a reusable mechanical, non-electronic infusion pump that does not require batteries or any electrical source. There are no alarms or displays. The VersaPump Infuser uses a spring as a source of energy to provide pressure for the subcutaneous infusion of the indicated human plasma-derived immunoglobulin solutions. The VersaPump Infuser is provided with a carrying case and User Manual. The carrying case allows the user to strap the VersaPump to their shoulder and walk around their environment during an infusion cycle. The VersaPump enclosure is made of synthetic polymer blend of glass reinforced polyphenylene ether and polystyrene, the spring is a 301 stainless steel spring, and the spring enclosure is made of synthetic polymer polyoxymethylene (POM/acetal).

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 rate when used with the VersaPump Infuser and include side-clamps for stopping the flow of fluid. The VersaPump 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 flow rate.

The VersaRate Plus variable flow rate controller is individually packaged, sterile, single use device. It may be used with the VersaPump Infuser to provide convenient control of the flow rate without having to select specific Infuset flow rate controller. The flat dial of the VersaRate Plus can be adjusted to set an appropriate flow rate of immune globulin solution or stop the fluid flow entirely. The VersaPump Infusion System User Manual includes information to guide users in the selection of the VersaRate Plus settings and SUB-Q patient administration sets to achieve the desired infusion flow rate.

The SUB-Q Administration Sets consist of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place while in use. The infusion set has a rigid PVC standard Luer lock at one end and a 90° 304 stainless steel needle mounted by a butterfly stabilizer at the other end. The two ends are connected by medical grade PVC tubing.

The main subject of this submission is VersaPump Infuser. The rest of the components of the VersaPump Infusion System are identical to the components used as part of the EMED SCIg60 Infusion System previously cleared by the FDA. Therefore, this submission contains safety and effectiveness data only for the VersaPump Infuser when used as a system utilizing the following commercially available syringes not sold or distributed by EMED:

- 20 mL BD syringe (model no. 302830)
- 20 mL Hizentra Prefilled Syringe (NDC 44206-458-96)
- 30 mL BD syringe (model no. 302832)
- 30 mL B. Braun syringe (model no. 4617304F)
- 35 mL Monoject syringe (model no. 1183500777 or 8881535762)

For the VersaPump to operate as a system, the flow rate controller (Infuset™ fixed flow rate control infusion set or VersaRate Plus ™ variable flow rate control infusion set) is connected to one of the above syringes via the Luer Lock. The patient administration set is then connected via Luer Lock connector to the flow controller. The patient administration set provides one or more needles that can be placed into subcutaneous tissue for the infusion. Depending on the number and gauge of the needle(s), and the selection/setting of the flow controller, the desired flow rate is provided. The VersaPump User Manual provides information on flow rates obtainable with various combinations of the VersaPump, EMED flow rate controllers, subcutaneous administration sets, and biologics.

V. INTENDED USE/INDICATIONS FOR USE

The VersaPump Infusion System is intended for the subcutaneous infusion of indicated fluids for patients in the home or hospital environment when administered by an adult according to the indicated fluid's product labeling and with specified models of subcutaneous infusion sets, flow controllers, and syringes. The system is intended for single patient, multiple use only.

The VersaPump Infusion System is intended for adult and pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional. The infusion system must be operated by an adult for use with pediatric patients

The VersaPump Infusion System is indicated for the subcutaneous infusion of:

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

Table 1: Intended Use/Indications for Use Comparison with the Predicate

Parameter	Predicate – EMED SCIg60 Infusion System (K222087)	Subject – EMED VersaPump Infusion System	Comparison
Intended Use	To pump fluids from a reservoir into a patient in a controlled manner	Intended for the subcutaneous infusion of indicated fluids for patients in the home or hospital environment when administered by an adult according to the indicated fluid's product labeling and with specified models of subcutaneous infusion sets, flow controllers, and syringes. The system is intended for single patient multiple use only.	SIMILAR[1]
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),	The VersaPump Infusion System is intended for the subcutaneous infusion of: • Cuvitru Immune Globulin Infusion (Human) 20%, manufactured by Takeda, • Gammagard Liquid, Immune Globulin Infusion (Human) 10%, manufactured by Takeda, • Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring,	SIMILAR[2]

Parameter	Predicate – EMED SCIg60 Infusion System (K222087)	Subject – EMED VersaPump Infusion System	Comparison
	• 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.	• Gamunex-C Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics • Gammaked Immune Globulin Subcutaneous (Human) 10%, manufactured by Grifols Therapeutics • Xembify Immune Globulin Subcutaneous (Human) 20%, manufactured by Grifols Therapeutics, and • Cutaquig Immune Globulin (Human), 16.5%, manufactured by Octapharma AG.	
Prescription or Over the Counter	Prescription	Prescription	SAME
Intended Population	Adult and pediatric (2 years and older)	Adult and pediatric (2 years and older)	SAME
Environment of Use	Hospital or home	Hospital or home	SAME

NOTE 1: Environment of use of the subject device and the predicate is identical but was listed in the intended use section which also clarifies that the Infuser is intended for single patient, multiple use. This difference does not raise different questions of safety and effectiveness.

NOTE 2: The proposed indications for use for the subject device are identical to that of the predicate. The system is prescribed to patients with immunodeficiency and indicated for the subcutaneous infusion of indicated immunoglobulin. The key difference between the subject device and the predicate is the Infuser design which is intended to interface with different syringe types and sizes. However, syringe type or size is irrelevant to the indication for use of the system. Syringe type and size impacts system flow rate performance which was rigorously tested during bench testing to confirm that safety and effectiveness were not impacted. Syringes compatible with the system are listed in a separate section of the User Manual that lists all compatible components of the system. The conducted Human Factors Validation Testing serves as objective evidence that the User Manual provides the users with sufficient information to understand how the device is used and what components are needed for the system to operate safely and effectively.

VI. TECHNOLOGICAL COMPARISON WITH PREDICATE DEVICE

The VersaPump Infusion System is not based on new technology, nor is it based on new clinical application of an existing technology.
The principle of action for the VersaPump Infusion System when compared to the predicate is identical. Both, the subject and predicate devices have 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 Plus variable flow rate controller. The flow control properties of the tubing follows the Poiseuille equation in that pressure, length of fluid path, diameter of fluid path, and viscosity of a fluid in a system directly influence resultant flow rate of that fluid.

Table 2: Comparison of Technological Characteristics with the Predicate

Parameter	Predicate – EMED SCIg60 Infusion System (K222087)	Subject – EMED VersaPump Infusion System	Comparison
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
Infuser Max Force	70 N (15.75 lbf)	36 N (8 lbf)	DIFFERENT[3]
Average Operating Pressure	1 bar	1 bar	SAME
Infuser Weight	1 lb.	1 lb.	SAME
Infuser Dimensions	10.2" x 2.6" x 2.6"	11.7" x 2.6" x 2.6	SIMILAR[4]
Infuser Sterility	Non-sterile	Non-sterile	SAME
Compatible Syringe/Fluid Container	BD 50 ml syringe, model no. 309653	• 20 mL BD syringe (model no. 302830) • 20 mL Hizentra Prefilled Syringe (NDC 44206-458-96) • 30 mL BD syringe (model no. 302832) • 30 mL B. Braun syringe (model no. 4617304F) • 35 mL Monoject syringe (model no. 1183500777 or 8881535762)	DIFFERENT[5]
Compatible Flow Controllers	Infuset, VersaRate, or VersaRate Plus	Infuset or VersaRate Plus	SAME
Compatible SUB-Q Administration Sets	SUB-Q, SAF-Q, or OPTFlow	SUB-Q, SAF-Q, or OPTFlow	SAME
Useful Life	4,200 cycles	2,000 cycles	DIFFERENT[6]
Infuser Intact Skin Contacting Material(s)	Noryl GFNI	Noryl GFNI	SAME
Alarms	None	None	SAME
Flow Rate Accuracy (%)	± 15	± 30	SIMILAR[7]

Parameter	Predicate – EMED SCIg60 Infusion System (K222087)	Subject – EMED VersaPump Infusion System	Comparison
• Infuset + SUB-Q Set • VersaRate Plus + SUB-Q Set	± 14-41	± 30-40	
Vertical Sensitivity • At +12” • At -12”	 Up to +6% from target flow rate Up to -4% from target flow rate	 Up to +5% from target flow rate Up to -5% from target flow rate	SIMILAR[8]

NOTE 3: The predicate and subject devices operate on the same operational principle – the user must open the Infuser, load the syringe with prescribed fluid into the Infuser, then close it. Upon closure, the Infuser's internal spring applies constant force upon a syringe. The force generated by the VersaPump Infuser is less than that generated by the predicate to offset the reduced size of the 20-35ml syringes used with VersaPump vs. the 50ml syringe used with the predicate. The conducted performance testing serves as objective evidence that difference in force between the subject and predicate devices does not impact safety or effectiveness of the device. Only those combinations of Infuset, VersaRate Plus and SUB-Q sets that provide flow rate performance in line with indicated immunoglobulin manufacturer recommendations are included in the VersaPump Infusion System User Manual. Combinations that allow for flow rate 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 VersaPump Infusion System is used as intended.

NOTE 4: The spring mechanism and the syringe models for the subject device are different than the predicate which results in different infuser length dimension. However, this size difference does not impact the safety or effectiveness of the device.

NOTE 5: Syringe type and size impacts system flow rate performance which was rigorously tested during bench testing to confirm that safety and effectiveness were not impacted, compared to the predicate.

NOTE 6: The indicated immunoglobulin is typically prescribed to be infused once or twice per week which would result in 19 years of use if the device is used twice per week. In the worst-case scenario, if the device is used once per day, 2,000 uses is equivalent to 5.5 years of use. Therefore, the subject device rated useful life of 2,000 uses provides an adequate useful life to infuse the intended fluids when used for the intended use and does not raise different questions of safety and effectiveness.

NOTE 7: Worst-case flow rate tolerances for the VersaPump Infusion System (up to ±40%) are within the worst-case flow rate tolerances of the predicate SCIg60 Infusion System (up to ±41%). Therefore, any differences in flow rate performance for specific system configurations are minor (i.e., fall within the predicate's maximum tolerance and

the immunoglobulin administration limits) and do not raise different questions of safety or effectiveness of the device when the VersaPump Infusion System is used as intended.

NOTE 8: A difference in the relative elevation between the needle tip and the syringe can result in variation in the flow rate performance because of earth's gravity and the mass of the fluid (hydraulic head in fluid mechanics). To determine the influence of vertical differences between the VersaPump Infuser and the point of fluid exiting the patient administration set, bench top performance testing was conducted. Vertical sensitivity was characterized and estimated to be within 5% per 12 inches at worst case. The vertical sensitivity of the VersaPump Infusion System for the infusion of indicated immunoglobulin solutions and standard expected flow rates were taken into account, and only those Infuset/VersaRate Plus and SUB-Q set combinations that meet label requirements for administration of each of the indicated immunoglobulin solutions were identified as suitable for use. These combinations were included in the VersaPump Infusion System User Manual as those that should be used to achieve desired flow rates. Therefore, minor difference in vertical sensitivity does not raise different questions of safety or effectiveness of the device when the VersaPump Infusion System is used as intended.

VII. PERFORMANCE DATA

No clinical study is included in this submission.

As recommended by FDA guidance, "Infusion Pumps Total Product Life Cycle" issued December 2, 2014, EMED has developed a Safety Assurance Case (SAC) to demonstrate that hazardous situations resulting from the design, intended use, and reasonably foreseeable misuse of the device have been appropriately mitigated. The supporting assurance arguments confirmed that:

- potential risks have been mitigated and the residual risk is acceptable,
- design verification and validation of the device is acceptable,
- device reliability is acceptable,
- the device meets its essential performance requirements.

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility

The VersaPump Infusion System has been evaluated for biocompatibility and is acceptable for its intended use. The biocompatibility evaluation of the VersaPump Infuser was conducted in accordance with the international standard EN ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA.

Design Verification

Various performance tests were conducted to provide objective evidence that the VersaPump Infuser retains its mechanical properties and functions as a system which include:

- Visual/Functional
- System Flow Rate Characterization and Performance
- Life Cycle testing
- Drop Test
- Cleaning
- Usability Evaluation

The aforementioned tests were completed compliant with/referencing the following standards, where applicable:

- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- IEC 62366-1:2015 Medical devices part 1, Application of usability engineering to medical devices
- ISO 28620:2020 Medical devices – Non-electrically driven portable infusion devices (Standard used to perform the Drop Test – reference only)

VIII. FINAL CONCLUSION

The data presented herein for the EMED Technologies Corporation VersaPump Infusion System demonstrates substantial equivalence to the predicate device and provides infusion rates consistent with the FDA approved human plasma-derived immunoglobulin labeling, when used as directed.