February 16, 2024

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

Re: K240148
Trade/Device Name: SCIg60 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PKP
Dated: January 18, 2024
Received: January 19, 2024

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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240148

Device Name
SCIg60 Infusion System

Indications for Use *(Describe)*
The SCIg60 Infusion System is intended for the subcutaneous infusion of indicated fluids in the home or hospital environment for adult or pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional.

The SCIg60 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

The SCIg60 Infuser Pump is intended for single patient, multiple use only, while flow controller and patient administration sets are single-use only.

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.

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

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510(k) Summary

Prepared on: 2024-01-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EMED Technologies Corporation
Applicant Address	1262 Hawks Flight Court Suite 200 EL Dorado Hills CA 95762 United States
Applicant Contact Telephone	916-932-0071
Applicant Contact	Mrs. Olena Whalen
Applicant Contact Email	owhalen@emedtc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SCIg60 Infusion System (FP-0010002)
Common Name	Infusion pump
Classification Name	Immunoglobulin G (Igg) Infusion System
Regulation Number	880.5725
Product Code(s)	PKP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222087	SCIg60 Infusion System	PKP

Device Description Summary

21 CFR 807.92(a)(4)

The EMED SCIg60 Infusion System consists of the SCIg60 Infuser (Pump), a 50 mL Luer lock syringe, a flow rate infusion set (either Infuset [fixed rate] flow control infusion set, VersaRate adjustable flow rate infusion set, or VersaRate Plus adjustable flow rate infusion set), and a commercially available subcutaneous (SUB-Q) infusion sets that utilize a standard Luer Lock style connector.

The SCIg60 Infuser is a reusable mechanical, non-electronic ambulatory infusion pump that does not require batteries or any electrical source. The SCIg60 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 SCIg60 Infuser is provided with a carrying case and User Manual. The SCIg60 Infuser enclosure is made of synthetic polymer blend of glass reinforced polyphenylene ether and polystyrene, the spring is made of stainless steel, and the spring enclosure is made of a blend of modified polyphenylene oxide and fibrous glass.

The Infuset flow control infusion set is an individually packaged, sterile, single-use device. It is assembled from standard Luer lock 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, and include side-clamps for stopping and starting the flow of fluid. The SCIg60 Infusion System User Manual includes information to guide users in the selection of Infuset flow control infusion set and SUB-Q infusion sets to achieve the desired infusion rates.

The VersaRate or VersaRate Plus adjustable flow rate infusion set are individually packaged, sterile, single-use devices. It is assembled from standard Luer lock components, PVC microbore tubing and a dial made of polycarbonate, styrene-ethylene-butylene (VersaRate) or polycarbonate, polyoxymethylene (VersaRate Plus). They may be used with the SCIg60 Infuser to provide convenient control of the flow rate without having to select specific Infuset flow control infusion set. 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 Infuset, VersaRate or VersaRate Plus

settings and SUB-Q infusion sets to achieve the desired infusion rates.

The following commercially available syringes not sold or distributed by EMED are compatible with SCIg60 Infusion System:
- BD 50 mL syringe (model no. 309653)
- Hizentra® 50 mL Prefilled Syringe (Model / Carton NDC# 44206-455-25)

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SCIg60 Infusion System is intended for the subcutaneous infusion of indicated fluids in the home or hospital environment for adult or pediatric patients (2 years and older) that require subcutaneous infusion of fluid medication prescribed by a healthcare professional.

The SCIg60 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

The SCIg60 Infuser Pump is intended for single patient, multiple use only, while flow controller and patient administration sets are single-use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed indications for use for the subject device are identical to that of the predicate. The system is intended for the subcutaneous infusion of indicated immunoglobulin. The Hizentra 50 mL Prefilled Syringe was added as one of the syringes compatible with SCIg60 Infusion System. No new biologics have been added to the indications for use. Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring is already indicated for use with SCIg60 Infusion System. The change does not constitute a new intended use/indications for use. Syringes compatible with the system are listed in the subject device's Instructions for Use in the list of compatible syringes.
Additionally, while the intended population did not change and the SCIg60 Infuser remains for single patient, multiple use, while flow controller and patient administration sets are single-use only – these details are now specified in the indications for use statement.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device. No design changes were made to the SCIg60 Infuser or any of the infusion sets in order to be compatible with the Hizentra 50 mL Prefilled Syringe. Since Hizentra Immune Globulin Subcutaneous (Human) 20%, manufactured by CSL Behring is already indicated for use with SCIg60 Infusion System, adding the Hizentra 50 mL Prefilled Syringe as compatible with the system does not raise new questions of safety and effectiveness in terms of drug-device compatibility. The syringe fitment and flow rate accuracy against Hizentra prescribing information has been verified during bench testing to confirm that safety and effectiveness were not impacted when used in the same manner as the predicate device. The physical or geometrical differences between the syringe models are negligible hence there is no difference between the two syringe models in terms of the SCIg60 Infusion System usability.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Clinical testing is not applicable for this submission.

The following testing was performed in support of this submission:
- Functional/Syringe Fitment Verification with the Hizentra 50 mL Prefilled Syringe,
- System Flow Rate Performance Verification with the Hizentra 50 mL Prefilled Syringe.

The non-clinical testing performed demonstrates that the EMED Technologies Corporation SCIg60 Infusion System, including the SCIg60 Infuser, Infuset flow control extension sets, VersaRate and VersaRate Plus flow controllers, used with SUB-Q patient administration sets, is substantially equivalent to the predicate device and provides infusion rates consistent with the FDA approved human plasma-derived immunoglobulin labeling, when used as directed.