DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 1, 2016

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

Re: K161906
Trade/Device Name: SCIg60 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: PKP
Dated: October 28, 2016
Received: October 31, 2016

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. 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); 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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161906

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 60 ml 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)

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)*

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510(k) Summary

K161906

Summary Prepared: December 1, 2016

General Information
Classification Class II
Trade Name SCIg60 Infusion System
Common Name: Infusion Pump
Classification Name and Reference: Pump, Infusion
Regulation: 21 CFR §880.5725
Product Code: PKP (immunoglobulin g (IgG) infusion system)

Submitter Peter Kollings
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El Dorado Hills, Ca
Tel: 916.932.0071
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General
This 510k submission for premarket clearance of the SCIg60 Infusion System is intended to expand the indications for use of the K142319 predicate to include infusion of the following human plasma-derived immunoglobulin solutions:

- Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Baxalta),
- Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Baxalta)

Beyond the expanded indications for use and associated updates to labeling, the SCIg60 Infusion System that is the subject of this submission is identical to that of the predicate in terms of principle of action, design, materials, functionality, and general performance.

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).

Comparison of Indications for Use of Subject and Predicate devices
The proposed indications for use of the SCIg60 Infusion System are identical to that of the predicate with the exception that infusion of Gammagard and Cuvitru are included.

The additional biological products being added to the SCIg60 Infusion System labeling have similar physicochemical characteristics to Hizentra with regard to composition, purity, presence

of trace contaminants, formulation and function. Any differences do not raise new issues of safety or effectiveness or alter the intended therapeutic effect because the principle of action, labeling, and overall design the SCIg60 Infusion System account for and accommodate such variations in human-plasma derived immunoglobulin solutions.

Primary Predicate Device(s)
K142319, SCIg60 Infusion System

Device Description
The EMED SCIg60 Infusion System consists of the SCIg60 Infuser, the Infuset™ flow control extension set and 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 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 pre-determined 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.

SCIg60 Infusion System should be used in accordance with its directions for use.

Technological Characteristics
The overall principle of action for the SCIg60 Infusion System consists of a constant pressure 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). 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 rates of that fluid.

The SCIg60 Infuser, Infuset™ flow control extension sets, and SUB-Q patient administration sets are identical to those presented in K142319.

The total flow rate range of the SCIg60 Infusion System has been adjusted from 12 – 52 ml/hr to 11 – 145 ml/hr to reflect the manufacturer-recommended total flow rates of the additional indicated immunoglobulin biologics. The increased upper limit of the total flow rate range does not represent a change in SCIg60 Infusion System design or performance, but instead reflects the expanded indications for use: the Prescribing Information for several of the proposed immunoglobulin solutions allow for greater total and per-site flow rates than Hizentra (the indicated biologic for the predicate). Additionally, manufacturers of proposed immunoglobulin solutions may also allow for use of more than 4 needles at once, thereby allowing for further increases in the upper limit of the total flow range performance range when compared with the predicate.

It is noted that the SCIg60 Infusion System instructions for use include only those combinations of Infuset 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 are not provided. Therefore, the increased upper limit of the total flow rate range is acceptable in terms of clinical use as well as compliance with flow rate recommendations provided by immunoglobulin solution manufacturers.

Summary of Performance Testing

A safety assurance case for the SCIg60 Infusion System was provided, as recommended by the FDA guidance document, Infusion Pumps Total Product Life Cycle. The stated top-level claim of the assurance case is:

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

The safety assurance case defined the device system, including the indications for use, patient types, users, use conditions, environments of use, and list of specific devices covered by the assurance case. The supporting sub-claims of the assurance case included the following:

- Device design is adequately verified and validated
- Device associated risks are completely identified and adequately mitigated
- Device is adequately reliable to ensure safety over device use life

The assurance case included mitigations of risks related to the following hazards:

- Operational Hazards
- Hardware Hazards
- Mechanical Hazards
- Environmental Hazards
- Biological and Chemical Hazards
- Use Hazards

The assurance case identified and claimed mitigation of the following device system level hazards:

- Infusion Delivery Error
- Traumatic Injury
- Incorrect Therapy
- Biological or Chemical Contamination

The following testing and evaluations were covered in the Safety Assurance Case:

- Infusion flow rate testing with SCIg60 Infusion System and indicated human plasma-derived immunoglobulin solutions.

- Infusion flow rate testing with combinations of SCIg60 Infuser, Infuset™ extension sets, and SUB-Q patient administration sets with simulated test fluid for the indicated human plasma-derived immunoglobulin solutions.

- Validation of simulated test fluids.

- Influence of elevation on flow rate for indicated human plasma-derived immunoglobulin solutions.

- Human factors validation of the SCIg60 Infusion System.

- Compatibility of each indicated human plasma-based immunoglobulin solution with the SCIg60 Infusion System related to adverse impact to either the SCIg60 Infusion System or the indicated fluids. The drug-device compatibility data referenced in K142319 for Hizentra was leveraged for Gammagard and Cuvitru after a comparison of factors that could impact the results of drug-device compatibility (e.g., pH and concentration).

- Reliability, biocompatibility, sterility and shelf life data were incorporated by reference to data from K142319.

The SCIg60 Infusion System includes directions for the selection of Infuset™ flow control extension sets and SUB-Q patient administration set combinations in order to achieve desired infusion rates for each of the indicated human plasma-derived immunoglobulin solutions, in accordance with the following tables:

Hizentra

First Infusion of Hizentra

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24
	4	39	10	FP-0010009	SUB-409-G24
27	2	25	13	FP-0010005	SUB-260
	4	47	12	FP-0010004	SUB-410

Standard Infusions of Hizentra

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	12	12	FP-0010008	SUB-109-G24
		16	16	FP-0010007	SUB-109-G24
	2	26	13	FP-0010010	SUB-209-G24
		35	18	FP-0010009	SUB-209-G24
	3	39	10	FP-0010009	SUB-309-G24
		51	17	FP-0010005	SUB-309-G24
	4	39	10	FP-0010009	SUB-409-G24
		52	13	FP-0010005	SUB-409-G24
27	1	14	14	FP-0010009	SUB-109-G27

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
		17	17	FP-0010004	SUB-109-G27
	2	25	13	FP-0010005	SUB-260
		30	16	FP-0010004	SUB-260
	3	43	14	FP-0010004	SUB-320
	4	47	12	FP-0010004	SUB-410

Gammagard

Initial Infusion of Gammagard (patients weighing less than 40kg)

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	2	25	12	FP-0010014	SUB-209-G24
	4	29	7	FP-0010011	SUB-409-G24
	5	63	13	FP-0010008	SUB-512-G24
27	1	13	13	FP-0010013	SUB-109-G27
	2	25	12	FP-0010011	SUB-260
	5	57	11	FP-0010008	SUB-509

Maintenance Infusions of Gammagard (patients weighing less than 40kg)

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	15	15	FP-0010013	SUB-109-G24
	2	25	12	FP-0010014	SUB-209-G24
		29	15	FP-0010011	SUB-209-G24
	4	29	7	FP-0010011	SUB-409-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	13	13	FP-0010013	SUB-109-G27
	2	25	12	FP-0010011	SUB-260
	3	51	17	FP-0010008	SUB-320
	5	57	11	FP-0010008	SUB-509
	6	88	15	FP-0010007	SUB-609

Initial Infusion of Gammagard (patients weighing 40kg or more)

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	15	15	FP-0010013	SUB-109-G24
	2	25	12	FP-0010014	SUB-209-G24
		29	15	FP-0010011	SUB-209-G24
	4	29	7	FP-0010011	SUB-409-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	13	13	FP-0010013	SUB-109-G27
	2	25	12	FP-0010011	SUB-260
	3	51	17	FP-0010008	SUB-320
	5	57	11	FP-0010008	SUB-509
	6	88	15	FP-0010007	SUB-609

Maintenance Infusions of Gammagard (patients weighing 40kg or more)

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	15	15	FP-0010013	SUB-109-G24
		24	24	FP-0010014	SUB-109-G24
	2	25	12	FP-0010014	SUB-209-G24
		29	15	FP-0010011	SUB-209-G24
	3	59	20	FP-0010008	SUB-309-G24
	4	29	7	FP-0010011	SUB-409-G24
		94	24	FP-0010007	SUB-409-G24
	5	63	13	FP-0010008	SUB-512-G24
	6	95	16	FP-0010007	SUB-612-G24
27	1	13	13	FP-0010013	SUB-109-G27
		21	21	FP-0010014	SUB-109-G27
		23	23	FP-0010011	SUB-109-G27
	2	25	12	FP-0010011	SUB-260
		47	24	FP-0010008	SUB-260
	3	51	17	FP-0010008	SUB-320
		71	24	FP-0010007	SUB-320
	4	80	20	FP-0010007	SUB-410
	5	57	11	FP-0010008	SUB-509
		121	24	FP-0010010	SUB-509
	6	88	15	FP-0010007	SUB-609

Cuvitru

First 2 Infusions of Cuvitru

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	11	11	FP-0010008	SUB-109-G24
		14	14	FP-0010007	SUB-109-G24
		17	17	FP-0010010	SUB-109-G24
	2	20	10	FP-0010010	SUB-209-G24
		32	16	FP-0010009	SUB-209-G24
	3	35	12	FP-0010009	SUB-309-G24
		45	15	FP-0010005	SUB-309-G24
	4	49	12	FP-0010005	SUB-409-G24

Subsequent Infusions of Cuvitru

Needle Gauge	Number of needles	Total Flow Rate (ml/hr)	Approx. Per Site Flow Rate (ml/hr)	Infuset™ Reorder Number	SUB-Q Set
24	1	11	11	FP-0010008	SUB-109-G24
		14	14	FP-0010007	SUB-109-G24
		17	17	FP-0010010	SUB-109-G24
		31	31	FP-0010005	SUB-109-G24
	2	20	10	FP-0010010	SUB-209-G24
		32	16	FP-0010009	SUB-209-G24
		42	21	FP-0010005	SUB-209-G24
		94	47	FP-0010004	SUB-209-G24
	3	35	12	FP-0010009	SUB-309-G24
		45	15	FP-0010005	SUB-309-G24
		118	39	FP-0010004	SUB-309-G24
	4	49	12	FP-0010005	SUB-409-G24
		145	36	FP-0010004	SUB-409-G24

Summary of Substantial Equivalence

The performance data demonstrates that the EMED Technologies Corporation SCIg60 Infusion System 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.