Repro-Medical System, Inc., dba Koru Medical Systems
% Kachi Enyinna
Consultant
510K Technology Group LLC
17 Orchard Terrace
East Arlington, Massachusetts 02474

April 29, 2022

Re: K214045
Trade/Device Name: FreedomEdge Syringe Infusion System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 22, 2022
Received: March 23, 2022

Dear Kachi Enyinna:

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.
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)*

Device Name
FreedomEdge® Syringe Infusion System

Indications for Use *(Describe)*

The FreedomEdge® Syringe Infusion System consists of the following components:

- FreedomEdge® Syringe Driver
- Precision Flow Rate Tubing™
- HIgH-Flo Subcutaneous Safety Needle Sets™
- HIgH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration.

The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

For Immunoglobulin Administration:

The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: 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% Liquid (manufactured by CSL Behring®) and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

For EMPAVELI™ (pegcetacoplan) Administration:

The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion with EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.

For Intravenous Antibiotic Administration:

The Freedom Integrated Syringe Infusion System with the FreedomEdge® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling:

Ertapenem, Meropenem, Oxacillin, and Tobramycin.

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

I. SUBMITTER

Repro-Med Systems, Inc. dba Koru Medical Systems
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Date Prepared: December 23, 2021

II. DEVICE

Name of Device: FreedomEdge® Syringe Infusion System
Common or Usual Name: Infusion Pump
Classification Name: Pump, Infusion (21CFR 880.5725)
Regulatory Class: II
Product Code: FRN, FPA, PKP

III. PREDICATE DEVICE

FreedomEdge® Syringe Infusion System (K211206)

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The FreedomEdge® Syringe Infusion System is a single-channel, volumetric infusion pump. The FreedomEdge® Syringe Infusion System consists of four primary components:

1. FreedomEdge® Syringe Driver,
2. Precision Flow Rate Tubing™ and

3. HIgH-Flo Subcutaneous Safety Needle Set™, or
4. HIgH-Flo Super26™ Subcutaneous Safety Needle Set

1. FreedomEdge® Syringe Driver:

The FreedomEdge® Syringe Driver (non-sterile) in combination with Precision Flow Rate Tubing™ (sterile) and HIgH-Flo Safety Needle Sets (sterile) makes up the FreedomEdge® Syringe Infusion System. The FreedomEdge® Syringe Driver is a non-sterile, reusable non-electric driver that infuses immunoglobulins and Pegcetacoplan subcutaneously and antibiotic solutions intravenously to patients.

The FreedomEdge® driver is an ambulatory device designed to accommodate a BD Luer-Lok™ 20mL syringe, Catalog No.: 302830 and 301031, BD Luer-Lok™ 30mL syringe, Catalog No.: 301033 and Hizentra® 20 ml prefilled syringe. The pump uses a constant force spring mechanism to apply pressure to the plunger-end syringe.

The FreedomEdge® Syringe Infusion System is assembled by loading the syringe with tubing into the FreedomEdge® driver.

2. Precision Flow Rate Tubing™:

The FreedomEdge® Syringe Infusion System includes a range of Freedom Precision Flow Rate Tubing™ (provided sterile). The tubing ranges from F0.5 to F2400. Each F-number provides a different level of flow restriction, which, when combined with the viscosity of the medication, provides a controlled delivery in an all-mechanical system. The tubing sets connect at one end to the syringe being used and on the other end to the Subcutaneous Safety Needle Sets or directly on venous catheters for intravenous infusions as needed.

3. HIgH-Flo Needles Sets:

The HIgH-Flo Subcutaneous Safety Needle Sets™
The HIgH-Flo Subcutaneous Safety Needle Sets™ (provided sterile) are used to administer drugs to the subcutaneous layers using small needles attached to the skin. Subcutaneous needles come in different lengths to administer immunoglobulins, pegcetacoplan, and antibiotics.

Subcutaneous Safety Needle Sets come in multiple configurations (1, 2, 3, 4, 5, 6 needle sites). Needles are available in 4mm, 6mm, 9mm, 12mm, and 14mm lengths combined with 24 or 26 Gauge. Using the Y-Connector, the patient can have up to 8 sites for drug delivery.

The HIgH- Flo Subcutaneous Safety Needle Sets™ also allow each needle to be enclosed between the wings after use.

The HIgH-Flo Super26™ Subcutaneous Needle Sets

The HIgH-Flo Super26™ Subcutaneous Needle Sets are sterile, non-pyrogenic, single use, Subcutaneous Administration Sets, comprised of a Super 26-gauge needle assembly, combined with 24-gauge needle tubing and are intended for the delivery of medication to the subcutaneous tissue. Each set consists of a sterile infusion set and a commercially available adhesive dressing used to hold the device in place. The infusion set is a 90-degree, 26-gauge stainless steel needle, mounted to a butterfly winged safety closure on one end which is used to close the set upon completion. The other end consists of a luer lock which connects to PVC medical grade tubing. Additionally, each tubing set is equipped with a slide clamp used to stop flow, immediately as needed. HIgH-Flo Super 26™ Subcutaneous Needle Sets are available as a single set, as well as 2-needle, 3-needle, 4-needle, 5-needle, 6-needle, sets; through use of a Y-connector, 7-needle and 8 needle sets may also be assembled.

The purpose of this premarket notification is to request a modification to the indications for use to include the addition of the drug EMPAVELI™ (pegcetacoplan) injection 1080/20 mL solution (manufactured by Apellis®) for subcutaneous infusion using the FreedomEdge® Syringe Infusion System.

V. INDICATIONS FOR USE

INTENDED USE

The FreedomEdge® Syringe Infusion System is intended for the intravenous or subcutaneous infusion of medications and fluids in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

Intended population: adults and pediatrics.

INDICATIONS FOR USE

The FreedomEdge® Syringe Infusion System consists of the following components:

- FreedomEdge® Syringe Driver
- Precision Flow Rate Tubing™
- HIgH-Flo Subcutaneous Safety Needle Sets™
- HIgH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration.

The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

For Immunoglobulin Administration:

The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: 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% Liquid (manufactured by CSL Behring®) and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

For EMPAVELI™ (pegcetacoplan) Administration:

The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion with EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.

For Intravenous Antibiotic Administration:

The Freedom Integrated Syringe Infusion System with the FreedomEdge® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling:

Ertapenem, Meropenem, Oxacillin, and Tobramycin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Indications for Use Comparison

The table below includes a comparison of the indications for use between the new device and that of the predicate device:

Table 1. Indications for Use Comparison

	Predicate Device (K211206) **FreedomEdge® Syringe Infusion System**	**Subject Device** **FreedomEdge® Syringe Infusion System**
	Modified Indications for Use	**Modified Indications for Use**
Indications	The FreedomEdge® Syringe Infusion System is indicated for the intravenous or subcutaneous infusion of medications and fluids in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The FreedomEdge® Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: 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% Liquid (manufactured by CSL Behring®) and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration. The FreedomEdge® Syringe Infusion System with the FreedomEdge® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: ertapenem, meropenem, oxacillin, and tobramycin. The FreedomEdge® Syringe Infusion System consists of the following components: • FreedomEdge® Syringe Driver • Precision Flow Rate Tubing™ • HIgH-Flo Subcutaneous Safety Needle Sets™ • HIgH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cuvitru®, Immune Globulin Infusion (Human) 20%	The FreedomEdge® Syringe Infusion System consists of the following components: • FreedomEdge® Syringe Driver • Precision Flow Rate Tubing™ • HIgH-Flo Subcutaneous Safety Needle Sets™ • HIgH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration. The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96). **For Immunoglobulin Administration:** The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); Hizentra®, Immune Globulin

	Predicate Device (K211206) FreedomEdge® Syringe Infusion System	Subject Device FreedomEdge® Syringe Infusion System
	Modified Indications for Use	**Modified Indications for Use**
	(manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration. The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 mL syringe (US Reference number: 302830*), BD 30 mL syringe (US Reference number: 302832**), and 20 mL single-use pre-filled syringe (NDC 44206-458-96). *Model no. 301031 is the non-sterile version of BD® 20 ml syringe sold by BD **model no. 301033 is the non-sterile version of BD® 30 ml syringe.	Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. **For EMPAVELI™ (pegcetacoplan) Administration:** The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion with EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling. **For Intravenous Antibiotic Administration:** The Freedom Integrated Syringe Infusion System with the FreedomEdge® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: Ertapenem, Meropenem, Oxacillin, and Tobramycin.
Prescription or Over the Counter	Prescription	Prescription
Intended Population	Adult and pediatric	Adult and pediatric
Environment of Use	Hospital, ambulatory, or home	Hospital, ambulatory, or home

Justification of differences in Indications for Use of Subject and Predicate Device

The indications for use statement for the FreedomEdge® Syringe Infusion System is not identical to the predicate device. The submission expands on the currently cleared indications for use to include the EMPAVELI™ (pegcetacoplan) injection 1080/20 mL solution (manufactured by Apellis®) for use with the infusion system. The difference between the subject device and predicate device infusion system is the inclusion of the

EMPAVELI™ (pegcetacoplan) injection 1080/20 mL solution into the indications for use.

Compatibility of the EMPAVELI™ (pegcetacoplan) injection 1080/20 mL solution with the FreedomEdge® infusion system specifically has been verified through performance testing. The change to device indications do not significantly affect safety or effectiveness as the changes do not create new risks or significantly modify existing risk. The change in indications for use does not raise different questions of safety and effectiveness and, therefore, does not preclude a meaningful comparison with the predicate device.

The routes of administration for the system, intravenous, and subcutaneous were cleared in the predicate device.

Discussions of differences in intended population
The intended population for the subject device is identical to the predicate device. EMPAVELI™ is specifically indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

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

Device configuration
The table below compares configuration of the infusion system between the subject device and that of the predicate device:

Table 2. Device Configuration Comparison

Predicate **K211206** FreedomEdge® Syringe Infusion System	**Subject Device** **(unknown)** FreedomEdge® Syringe Infusion System
1. The FreedomEdge® Syringe Driver 2. Precision Flow Rate Tubing™ 3. HIgH-Flo™ Subcutaneous Safety Needle Sets (24G, 26G) 4. HIgH-FLO Super26™ Subcutaneous Needle Sets	1. The FreedomEdge® Syringe Driver 2. Precision Flow Rate Tubing™ 3. HIgH-Flo™ Subcutaneous Safety Needle Sets (24G, 26G) 4. HIgH-FLO Super26™ Subcutaneous Needle Sets

Discussions of differences in system configuration

The FreedomEdge® Syringe Infusion System (subject device) configuration is identical to the predicate device. There is no change to the system as a result of the IFU medication.

Table 3 presents a tabular comparison of the technological characteristics between the proposed device and predicate device with an assessment of differences between subject device and predicate device and why the differences do not introduce new or different questions of safety and effectiveness.

Table 3. Comparison of Predicate and Subject Device

Technological Characteristics	**FreedomEdge® Syringe Infusion System (K211206)**	**FreedomEdge® Syringe Infusion System (Subject Device)**	**Comparison**
Spring Type	Negator	Negator	Same
Winding of Spring	FreedomEdge® syringe driver: Manual lever used to tension negator constant force spring	FreedomEdge® syringe driver: Manual lever used to tension negator constant force spring	Same
On / Off Control	Manual switch	Manual switch	Same
Housing	Molded ABS	Molded ABS	Same
Syringe Type	BD® 20 mL syringe (US Reference number: 302830) BD® 30 mL syringe (US Reference number: 302832) 20 mL single-use pre-filled syringe (NDC 44206-458-96).	BD® 20 mL syringe (US Reference number: 302830) BD® 30 mL syringe (US Reference number: 302832) 20 mL single-use pre-filled syringe (NDC 44206-458-96).	Same
Tubing Length (inches)	20	20	Same
Tubing Diameter (inches)	HIgH-Flo™ Subcutaneous Safety Needle Sets (24G and 26G) 0.0190 ± 0.001” HIgH-FLO Super26™ Subcutaneous Needle Sets 00.033 + 0.002”/-0.001”	HIgH-Flo™ Subcutaneous Safety Needle Sets (24G and 26G) 0.0190 ± 0.001” HIgH-FLO Super26™ Subcutaneous Needle Sets 00.033 + 0.002”/-0.001”	Same
Tubing Material	Medical Grade PVC Plastic	Medical Grade PVC Plastic	Same
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Gauge	24 Gauge Needle Sets 26 Gauge Needle Sets	24 Gauge Needle Sets 26 Gauge Needle Sets	Same

Technological Characteristics	FreedomEdge® Syringe Infusion System (K211206)	FreedomEdge® Syringe Infusion System (Subject Device)	Comparison
Needle Butterfly Wings Material	HIgH-Flo™ Subcutaneous Safety Needle Set Polypropylene HIgH-FLO Super26™ Subcutaneous Needle Sets Polypropylene with blue colorant (541790C Translucent blue, Marvel Industries, Inc.)	HIgH-Flo™ Subcutaneous Safety Needle Set Polypropylene HIgH-FLO Super26™ Subcutaneous Needle Sets Polypropylene with blue colorant (541790C Translucent blue, Marvel Industries, Inc.)	Same
Needle Lengths	4, 6, 9, 12, 14	4, 6, 9, 12, 14	Same
Needle Usage	Single Use	Single Use	Same
Packaging	Tubing and Needle Sets packaged sterile utilizing a nylon pouch (P/N 317050), for single patient use.	Tubing and Needle Sets packaged sterile utilizing a nylon pouch (P/N 317050), for single patient use.	Same
Prescription required	Yes	Yes	Same
Intended Population	Adult, Pediatric	Adult, Pediatric	Same
System Accuracy	Flow rates will fall between the minimum and maximum predicted values as specified in the IFU.	Flow rates will fall between the minimum and maximum predicted values as specified in the IFU.	Same
Sterilization Method	Syringe Driver is non-sterile; Needle Sets & Tubing sterilized via Gamma SAL 10^{-6}	Syringe Driver is non-sterile; Needle Sets & Tubing sterilized via Gamma SAL 10^{-6}	Same
Needle Set Configurations Available	**24 Gauge:** Available as a single-needle set, as well as 2-needle, 3-needle, 4-needle set; through use of a Y-connector, 5- needle, 6-needle, 7-needle and 8-needle sets may also be assembled. **26 Gauge:** Available as a single-needle set, as well as 2-needle, 3-needle, 4-needle, 5-needle, and 6-needle sets; through use of a Y-connector, 7-needle and 8-needle sets may also be assembled.	**24 Gauge:** Available as a single-needle set, as well as 2-needle, 3-needle, 4-needle set; through use of a Y-connector, 5- needle, 6-needle, 7-needle and 8-needle sets may also be assembled. **26 Gauge:** Available as a single-needle set, as well as 2-needle, 3-needle, 4-needle, 5-needle, and 6-needle sets; through use of a Y-connector, 7-needle and 8-needle sets may also be assembled.	Same
	Needle / **24 G** / **26 G** / **Super26**	**Needle** / **24 G** / **26 G** / **Super26**	Same

Technological Characteristics	FreedomEdge® Syringe Infusion System (K211206)				FreedomEdge® Syringe Infusion System (Subject Device)				Comparison
Residual Volumes for HIgH-Flo Needle Sets	**1**	0.4 ml	0.1 ml	0.4 ml	**1**	0.4 ml	0.1 ml	0.4 ml	
	2	0.7 ml	0.2 ml	0.7 ml	**2**	0.7 ml	0.2 ml	0.7 ml	
	3	1.1 ml	0.3 ml	1.1 ml	**3**	1.1 ml	0.3 ml	1.1 ml	
	4	1.4 ml	0.4 ml	1.4 ml	**4**	1.4 ml	0.4 ml	1.4 ml	
	5	2.0 ml (with Y-connector)	0.5 ml	1.8 ml	**5**	2.0 ml (with Y-connector)	0.5 ml	1.8 ml	
	6	2.3 ml (with Y-connector)	0.6 ml	2.1 ml	**6**	2.3 ml (with Y-connector)	0.6 ml	2.1 ml	
	7	2.7 ml (with Y-connector)	0.9 ml (with Y-connector)	2.7 ml (With Y-connector)	**7**	2.7 ml (with Y-connector)	0.9 ml (with Y-connector)	2.7 ml (With Y-connector)	
	8	1.0 ml (with Y-connector)	1.0 ml (with Y-connector)	3.0 ml (With Y-connector)	**8**	1.0 ml (with Y-connector)	1.0 ml (with Y-connector)	3.0 ml (With Y-connector)	

VII. PERFORMANCE DATA

The following performance data/non-clinical testing was provided in support of the substantial equivalence determination for the FreedomEdge® Syringe Infusion System. The infusion system does not contain software, electrical components, or alarms.

Device Performance	The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle"
Biocompatibility	The materials used in the Administration Set (tubing and needles) for the FreedomEdge® Syringe Infusion System comply with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", within a Risk Management Process and are considered to be biocompatible. Testing was conducted for the following tests: • Cytotoxicity • Sensitization • Irritation
Human Factors	Human factors studies were completed per the FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" (February 3, 2016). The human factors studies were conducted with the intended user population, use environment and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Reprocessing, Cleaning	AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. AAMI TIR30:2011(R)2016 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Document issued on March 17, 2015 amended June 9, 2017, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluations. ISO 17664:2017 – Processing of healthcare products – Information to be provided by the medical device manufacturer for the processing of medical devices. ANSI/AAMI/ISO 11737-1:2018 – Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product.

	NAMSA Technical Memorandum US033689 Rev. 1, Review and Comparison of the Koru Medical Systems Syringe Drive products to determine the Worst-Case Design for Cleaning and Low Level Disinfection Efficacy Studies.
Packaging	11607-1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
Sterility	ISO 11137-2:2013 *Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*.
MR Safety	ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment."

Safety Assurance

A safety assurance case is provided for the FreedomEdge® Syringe Infusion System, as recommended in the FDA guidance document, "Infusion Pumps Total Product Life Cycle."

The stated goal of the safety assurance case is:

- The FreedomEdge® Syringe Infusion System is adequately safe for its intended use.

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

- Device requirements are adequate, and design is adequately verified and validated.
- Device associated risks are completely identified and adequately mitigated.
- Device is adequately reliable to ensure safety over its service 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:

Device Performance

The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle

The FreedomEdge® Syringe Infusion System includes directions for the selection of Precision Tubing Sets, HIgH-Flo Subcutaneous Needle Sets, and HIgH-FLO Super26 Subcutaneous Needle Sets combinations in order to achieve desired infusion rates for each

of the indicated human plasma-derived immunoglobulin solutions and Pegcetacoplan solutions, in accordance with the following tables:

EMPAVELI™ 20 ml syringe Selected Flow Rate Combinations

The following tables indicate the max-min predicated flow rates per site with HIgH-Flo Subcutaneous Safety Needles Sets™ (Standard 26G) when used in combination with KORU Precision Flow Rate Tubing™ and the FreedomEdge® Syringe Infusion System with a 20 ml BD syringe for the subcutaneous use of EMPAVEL™.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, the prescriber should refer to drug package insert for the approximate maximum and minimum indicated infusion times.

HIgH-Flo 26G with Precision Tubing – Max-Min Flow Rate Per Site (ml/hr/site)

	F500	F600	F900	F1200	F2400
1 needle	18 – 42.2	19.4 - 45.8	22.3 - 53.6	22.9 - 58	27.7 - 72.9
2 needles	12.6 – 27.2	13.4 – 30.3	16.3 – 37.4	16.9 – 41.9	22.8 – 59.4

HIgH-Flo 26G with Precision Tubing – Max-Min Flow Rate Total (ml/hr)

		F600	F900	F1200	F2400
1 needle	18.6 – 42.2	19.4 - 45.8	22.3 - 53.6	22.9 - 58	27.7 - 72.9
2 needles	25.2 – 54.3	26.7 - 60.5	32.5 - 74.9	33.8 - 83.7	45.5 - 118.7

HIgH-Flo 26G with Precision Tubing – Min-Max Infusion Times (minutes)

	F500	F600	F900	F1200	F2400
1 needle	47 (28-65)	44 (26 – 62)	38 (22 – 54)	37 (21 – 52)	30 (16 – 43)
2 needles	35 (22-48)	35 (22 – 48)	27 (16-37)	25 (14 – 36)	18 (10 - 26)

The EMPAVELI™ label states that typical infusion time is approximately 30 minutes (if using 2 infusion sites) or approximately 60 minutes (if using one infusion site). Based on assessment of EMPAVELI™ labeling there is no identified patient risk for going faster or slower than this approximate infusion time.

Selected Flow Rate Combinations

Select Combinations of Flow Rates with HIgH-Flo Subcutaneous Safety Needle Sets™ (Standard 26G and 24G) when used in combination with Precision Flow Rate Tubing™ for use with Hizentra®, Cuvitru®, and Gammagard® Liquid.

Note: The following tables are only for the subcutaneous use of the immunoglobulin listed.

Hizentra – FreedomEdge® with 20 ml syringe							
Drug volume (ml)	**Flow Rate Tubing**	**HIgH-Flo Needle Set***	**Total Flow Rate (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
10	F120	RMS12609	8.2	8.2	10	1:12	Suggested start Peds
10	F180	RMS12609	10.5	10.5	10	0:57	Suggested start Peds
20	F275	RMS22609	17.1	8.5	10	1:10	Suggested start Peds
20	F600	RMS22609	29.6	14.8	10	0:40	Suggested start Peds
40	F600	RMS32609	33.9	11.3	13.3	1:10	Suggested start Adult
40	F900	RMS32609	44.3	14.8	13.3	0:54	Suggested start Adult
60	F900	RMS42609	49	12.3	15	1:13	Suggested start Adult
50	F2400	RMS32609	72.2	24.1	16.67	0:41	6th Infusion of biologic and beyond
100	F2400	RMS42609	85.5	21.4	25	1:10	6th Infusion of biologic and beyond(NEEDS TWO SYRINGES)
Hizentra - with FreedomEdge® with 30 ml syringe							
20	F600	RMS22609	22.5	11.2	10	0:53	Suggested start Peds
30	F900	RMS22609	28.3	14.2	15	1:03	Suggested start Adult
30	F2400	RMS22609	41.9	20.9	15	0:42	6th Infusion of biologic and beyond

Cuvitru – with FreedomEdge® with 20 ml syringe							
Drug volume (ml)	**Flow Rate Tubing**	**HIgH-Flo Needle Set***	**Total Flow Rate (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
10	F275	RMS12609	12.1	12.1	10	0:49	1st Two Infusions patients under 40kg
20	F275	RMS12609	12.1	12.1	20	1:39	1st Two Infusions patients under 40kg
20	F600	RMS22609	25.7	12.8	10	0:47	1st Two Infusions patients under 40kg
50	F600	RMS22609	25.7	12.8	25	1:57	1st Two Infusions patients over 40kg
60	F1200	RMS22609	37.1	18.6	30	1:37	Subsequent Infusions
60	F2400	RMS22409	110.5	55.4	30	0:32	Subsequent Infusions
60	F1200	RMS12409	55.3	55.3	60	1:05	Subsequent Infusions
100	F2400	RMS42409	132.8	33.2	25	0:45	Subsequent Infusions

Cuvitru – with FreedomEdge® with 30 ml syringe							
20	F500	RMS22609	12.9	12.9	20	1:32	1st Two Infusions patients under 40kg
30	F900	RMS22609	24.6	12.3	15	1:13	1st Two Infusions patients under 40kg
30	F2400	RMS12609	21.2	21.2	30	1:24	Maintenance Infusions
30	F1200	RMS12409	42.1	42.1	30	0:42	Maintenance Infusions

Gammagard Liquid – with FreedomEdge® with 20 ml syringe							
Drug volume (ml)	**Flow Rate Tubing**	**HIgH-Flo Needle Set***	**Total Flow Rate (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
20	F45	RMS12609	14.2	14.2	20	1:24	Patients under 40kg (Initial)
60	F120	RMS22609	39.8	19.9	30	1:30	Patients over 40kg (Initial)
100	F420	RMS42609	119.1	29.8	25	0:50	Patients over 40kg (maintenance infusions)
Gammagard Liquid – with FreedomEdge® with 20 ml syringe							
20	F120	RMS22609	30	15	10	0:40	Patients under 40kg(Initial)
30	F180	RMS22609	39.8	19.9	15	0:45	Patients over 40kg (Initial)
30	F120	RMS12609	27	27	30	1:06	Patients over 40kg (Maintenance)

*HIgH-Flo needle sets: The first number refers to the number of needles, the next two numbers refer to the needle gauge, and the last two numbers refer to the needle length (mm).

Hizentra® 20 ml Prefilled Syringe Selected Flow Rate Combinations

The following tables indicate the min-max predicated flow rates per site with HIgH-Flo Subcutaneous Safety Needles Sets™ (Standard 26G, 24G and Super26™) when used in combination with KORU Precision Flow Rate Tubing™ and the FreedomEdge® Syringe Infusion System with a 20 ml syringe for the subcutaneous use of Hizentra CIDP.

To determine the appropriate flow rate tubing and subcutaneous needle configuration, please refer to drug package insert for the maximum indicated flow rate and volume per infusion site for initial and subsequent infusions.

HIgH-Flo 26G with Precision Tubing – Min-Max Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	7 - 12.9	9.7 - 15.4	13.1 - 21.2	16.7 - 28.7	19.9 - 30.5	21.6 - 33.9	27.3 - 42	28.8 - 45.9	35.7 - 55.6
2 needles	3.8 - 7.1	5.4 - 8.7	7.6 - 12.6	10.1 - 18.2	12.6 - 19.6	14 - 22.5	19.2 - 30.3	20.7 - 34.6	28.7 - 46.9
3 needles	2.6 - 4.9	3.7 - 6	5.4 - 8.9	7.3 - 13.3	9.3 - 14.5	10.3 - 16.9	14.8 - 23.7	16.2 - 27.7	24 - 40.6
4 needles	2 - 3.7	2.9 - 4.6	4.2 - 6.9	5.7 - 10.5	7.3 - 11.5	8.2 - 13.5	12.1 - 19.5	13.3 - 23.2	20.6 - 35.8
5 needles	1.6 - 3	2.3 - 3.8	3.4 - 5.7	4.7 - 8.7	6 - 9.5	6.8 - 11.2	10.2 - 16.5	11.2 - 19.9	18.1 - 32
6 needles	1.3 - 2.5	1.9 - 3.2	2.9 - 4.8	3.9 - 7.4	5.1 - 8.1	5.8 - 9.6	8.8 - 14.4	9.8 - 17.4	16.1 - 28.9
7 needles	1.1 - 2.2	1.7 - 2.7	2.5 - 4.1	3.4 - 6.4	4.5 - 7.1	5.1 - 8.4	7.7 - 12.7	8.6 - 15.5	14.5 - 26.4
8 needles	1 - 1.9	1.5 - 2.4	2.2 - 3.7	3 - 5.7	4 - 6.3	4.5 - 7.5	6.9 - 11.4	7.7 - 13.9	13.2 - 24.2

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

HIgH-Flo Super26 with Precision Tubing – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	7.6 - 14.2	10.8 - 17.4	15.3 - 25.3	20.4 - 36.6	25.5 - 39.5	28.2 - 45.4	38.8 - 61.3	41.9 - 70	58.3 - 95.5
2 needles	4 - 7.5	5.7 - 9.3	8.3 - 13.9	11.4 - 21.1	14.7 - 23	16.5 - 27.1	24.3 - 39.2	26.7 - 46.7	41.7 - 72.5
3 needles	2.7 - 5.1	3.9 - 6.3	5.7 - 9.6	7.9 - 14.8	10.3 - 16.2	11.6 - 19.3	17.7 - 28.9	19.6 - 35	32.5 - 58.4
4 needles	2 - 3.9	2.9 - 4.8	4.3 - 7.3	6.1 - 11.4	7.9 - 12.5	9 - 15	13.9 - 22.8	15.5 - 28	26.6 - 48.9
5 needles	1.6 - 3.1	2.4 - 3.9	3.5 - 5.9	4.9 - 9.3	6.4 - 10.2	7.3 - 12.3	11.4 - 18.9	12.8 - 23.4	22.5 - 42.1
6 needles	1.4 - 2.6	2 - 3.2	2.9 - 5	4.1 - 7.8	5.4 - 8.6	6.2 - 10.4	9.7 - 16.1	10.9 - 20	19.5 - 36.9
7 needles	1.2 - 2.2	1.7 - 2.8	2.5 - 4.3	3.6 - 6.7	4.7 - 7.4	5.4 - 9	8.4 - 14	9.5 - 17.5	17.2 - 32.9
8 needles	1 - 2	1.5 - 2.4	2.2 - 3.8	3.1 - 5.9	4.1 - 6.6	4.7 - 7.9	7.5 - 12.4	8.4 - 15.6	15.4 - 29.6

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

HIgH-Flo 24G with Precision Tubing – Min-Max Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	8 - 15.1	11.5 - 18.7	16.8 - 28.2	23.2 - 43	29.9 - 47.1	33.8 - 55.8	50.3 - 81.7	55.6 - 98	88.8 - 156.3
2 needles	4 - 7.7	5.9 - 9.6	8.7 - 14.7	12.2 - 23	16 - 25.4	18.2 - 30.5	28.3 - 46.7	31.7 - 57.7	55.3 - 102.8
3 needles	2.7 - 5.2	4 - 6.5	5.9 - 10	8.3 - 15.7	11 - 17.4	12.5 - 21	19.7 - 32.7	22.2 - 40.9	40.2 - 76.6
4 needles	2 - 3.9	3 - 4.9	4.5 - 7.5	6.3 - 11.9	8.3 - 13.2	9.5 - 16	15.1 - 25.2	17 - 31.7	31.5 - 61.1
5 needles	1.6 - 3.1	2.4 - 3.9	3.6 - 6.1	5.1 - 9.6	6.7 - 10.7	7.7 - 12.9	12.2 - 20.4	13.8 - 25.8	26 - 50.8
6 needles	1.4 - 2.6	2 - 3.3	3 - 5.1	4.2 - 8.1	5.6 - 8.9	6.4 - 10.8	10.3 - 17.2	11.7 - 21.8	22 - 43.4
7 needles	1.2 - 2.2	1.7 - 2.8	2.6 - 4.3	3.6 - 6.9	4.8 - 7.7	5.5 - 9.3	8.9 - 14.9	10.1 - 18.9	19.2 - 38
8 needles	1 - 2	1.5 - 2.5	2.3 - 3.8	3.2 - 6.1	4.2 - 6.7	4.9 - 8.2	7.8 - 13.1	8.9 - 16.6	17 - 33.7

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

Clinical Evaluation

Clinical evaluation was not required to support submission and determination of substantial equivalence.

VIII. CONCLUSIONS

The FreedomEdge® Syringe Infusion System is substantially equivalent to the commercially available predicate device in terms of function, safety, performance, intended use, technology/principles of operation and mechanical properties. The non-clinical data support the safety of the device and performance testing demonstrate that the FreedomEdge® Syringe Infusion System meets the established specifications necessary for consistent performance to achieve its intended use as safely and as effectively as the predicate device and reference device and confirmed that the technological differences between the proposed device and predicate device do not raise different questions of safety or effectiveness. Based on performance testing results, the FreedomEdge® Syringe Infusion System, performs as intended and performs comparably to the predicate device that is currently marketed for the same intended use.