Repro-Medical System, Inc., dba Koru Medical Systems
Kachi Eniyinna
Consultant
24 Carpenter Road
Chester, New York 10918

Re: K211206
Trade/Device Name: FreedomEdge(R) Syringe Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, FPA, PKP
Dated: October 4, 2021
Received: October 4, 2021

Dear Kachi Eniyinna:

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,

Carolyn Dorgan
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211206

Device Name
FreedomEdge® Syringe Infusion System

Indications for Use *(Describe)*

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% (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 single-use pre-filled syringe (NDC 442096-458-96).

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.

Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
K211206

I. SUBMITTER

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Date Prepared: October 2, 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

Predicate Device: Integrated Catch-Up FREEDOM Syringe Driver Infusion System, K162613

Reference Device: KORU HIgH-Flo Super26™ Subcutaneous Safety Needle Set, K180843.

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 certain immunoglobulins 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 Freemdom60® driver.

2. Precision Flow Rate Tubing™:

The Freedom Integrated Syringe 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:

<u>The HIgH-Flo Subcutaneous Safety Needle Sets™</u>
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 and antibiotics per the indications for use.

Subcutaneous Safety Needle Sets comes 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 in accordance with the indication for use statement. 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 for the cleared infusion system. The major modifications to the current device are as follows:

1. **Device Configuration**
    a. **Removal of syringe driver** – The Subject device will only include use of only one syringe driver (FreedomEdge) instead of two syringe drivers cleared for use in the predicate device.
    b. **Addition of second needle set** – The HIgH-FLO Super26 Subcutaneous Needle cleared under K180843 is added for use with the system.

2. **Update Indication for Use** – The purpose of the device application is to expand the currently cleared indications for use to include the addition of Hizentra 20ml Prefilled syringe and HIgH-Flo Super26™ Subcutaneous Needle Set into the indications for use.

3. **Addition of Blue Colorant to Needle Butterfly Wings** – Addition of a blue colorant to the HIgH-Flo Super26™ Subcutaneous Safety Needle Sets. The blue colorant (541790C Translucent blue, Marvel Industries, Inc.) was added to the Super26™ needle hub assembly to help distinguish between the HIgH-Flow Subcutaneous Safety Needle Sets and HIgH-Flo Super26™ Subcutaneous Safety Needle Sets.

4. **Update Sterile Barrier (Packaging material)** – sterile devices will be packaged in a nylon film pouch, which once sealed, serves as the sterile barrier. The pouch material was updated from LDPE pouch, P/N 317036 to

Nylon pouch, P/N 317050.

5. **Flow Rate Accuracy** – the flow rate accuracy between the subject device and predicate device has changed from +/-8% to predicted minimum to maximum flow rates within those labeled per the Hizentra package insert for each combination of needle set and tubing.

V. INDICATIONS FOR USE

INTENDED USE

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

Intended population: adults and pediatrics.

INDICATIONS FOR USE

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% (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).

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 (K162613) Integrated Catch-Up FREEDOM Syringe Driver Infusion System	**Subject Device (K211206)** FreedomEdge® Syringe Infusion System
	Current configuration	**New configuration**
	Current Indications for Use as cleared August 31, 2017	**Modified Indications for Use**
Indications	The Integrated Catch-Up FREEDOM Syringe Driver Infusion System (ICFSDIS), which includes the FREEDOM60® and FreedomEdge® syringe pumps, 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 ICFSDIS is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Hizentra, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring); Gammagard Liquid, Immune Globulin Infusion (Human) 10% (manufactured by Shire); and Cuvitru Immune Globulin Infusion (Human) 20% (manufactured by Shire). The ICFSDIS is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling:	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.

	Predicate Device (K162613) Integrated Catch-Up FREEDOM Syringe Driver Infusion System	Subject Device (K211206) FreedomEdge® Syringe Infusion System
	Current configuration	**New configuration**
	Current Indications for Use as cleared August 31, 2017	**Modified Indications for Use**
	meropenem, ertapenem, oxacillin, and tobramycin. The FreedomEdge® Syringe Infusion System is indicated for use with the BD 20 ml (model no. 302830/301031) or BD 30 ml (model no. 301033) syringe. The FREEDOM60 Syringe Infusion System is indicated for use with the BD 60 ml syringe (model no. 309653).	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% (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.

	Predicate Device (K162613) Integrated Catch-Up FREEDOM Syringe Driver Infusion System	**Subject Device (K211206)** FreedomEdge® Syringe Infusion System
	Current configuration	**New configuration**
	Current Indications for Use as cleared August 31, 2017	**Modified Indications for Use**
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 a 20mL Hizentra Pre-Filled Syringe and the HIgH-Flo Super26™ Subcutaneous Needle Set to the infusion system. The difference in in between the subject device and predicate device infusion system are the inclusion of the 20mL Hizentra Pre-Filled Syringe and the HIgH-Flo Super 26™ Subcutaneous Needle Set into the indications for use.

Compatibility of prefilled syringe and HIgH-Flo Super26™ with the FreedomEdge infusion system specifically has been verified through performance testing. The FreedomEdge Syringe Infusion System will include a second needle set, the HIgH-Flo Super26™ Subcutaneous Needle Sets, in addition to the HIgH-Flo Subcutaneous Safety Needle Sets™. The HIgH-Flo Super26™ Subcutaneous Needle Set is cleared for use with the FreedomEdge syringe driver and Precision Flow Rate Tubing™ and 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. 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.

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 includes a comparison of the infusion system configuration between the new device and that of the predicate device:

Table 2. Device Configuration Comparison

Predicate **K162613** Integrated Catch-Up Freedom Syringe Driver Infusion System	**Subject Device** **K211206** FreedomEdge® Syringe Infusion System
1. The Freedom60® Syringe Driver 2. The FreedomEdge® Syringe Driver 3. Precision Flow Rate Tubing™ 4. HIgH-Flo™ Subcutaneous Safety Needle Sets (24G, 26G)	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 Subject device utilizes the same components from predicate device to form the subject device, FreedomEdge® Syringe Infusion System. The main difference is that the subject device is re-configured and packaged with only one syringe driver (FreedomEdge syringe driver) instead of the two syringe drivers (FREEDOM60™ syringe driver and FreedomEdge™ syringe driver) cleared for use in the predicate device. Also, in addition, the new configuration will include use of the HIgH-Flow Super26 Subcutaneous Needle in addition to the HIgH-Flo™ Subcutaneous Safety Needles Sets. The HIgH-Flo Super26™, as part of the subject device is similar to the HIgH-Flo Subcutaneous Safety Needle Sets™ but specifically used for higher flow rates. Both needle sets are intended for the delivery of medication to the subcutaneous tissue. The HIgH-Flo Super26™ is cleared for use with the FreedomEdge® syringe driver. The methods for HIgH-Flo Super26™ has been shown to be substantially equivalent in K180843, as a reference device.

The devices are furthermore, similar in technological characteristics with respect to providing intravenous or subcutaneous infusion of medications and fluids. While there are minor technological differences between the subject and predicate device, these differences do not introduce new or different questions of safety and effectiveness, as confirmed through the results of performance testing.

Table 3 and Table 4 presents a tabular comparison of the technological characteristics between the proposed device, and predicate device with an assessment of differences between them and why the difference between the subject device and predicate device do not introduce new or different questions of safety and effectiveness.

Table 3. Comparison of Predicate and Subject Device

Technological Characteristics	**Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System)** **(K162613)**	**FreedomEdge™ Syringe Infusion System** **(K211206)**	**Comparison**
Spring Type	Negator	Negator	Same
Winding of Spring	FREEDOM60® syringe driver: Manual knob used to tension negator constant force 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 winding of spring for FreedomEdge.
On / Off Control	Manual switch	Manual switch	Same
Housing	Molded ABS	Molded ABS	Same
Syringe Type	FreedomEdge BD® 20 mL syringe (US Reference number: 302830) BD 30 mL syringe (US Reference number: 302832) FREEDOM60® BD 50 mL syringe (model no. 309653)	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).	Different. Indications for Use now includes single use pre-filled syringe whereas the predicate does not. Syringe comes pre-filled with approved drug, Hizentra, ready to use in FreedomEdge syringe driver. Use of pre-filled syringe does not change intended use of infusion system device nor does it raise new questions of safety and effectiveness.

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FreedomEdge™ Syringe Infusion System (K211206)	Comparison
			BD 50 mL syringe is indicated for Freedom60 syringe driver only and therefore not part of Subject device.
Tubing Length (inches)	20	20	Same
Tubing Diameter (inches)	0.033 + 0.002"/-0.001"	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
Needle Butterfly Wings Material (HIgH-Flo™ Subcutaneous Safety Needle Set)	Polypropylene	Polypropylene	Same
Needle Lengths	4, 6, 9, 12, 14	4, 6, 9, 12, 14	Same
Needle Usage	Single Use	Single Use	Same

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FreedomEdge™ Syringe Infusion System (K211206)	Comparison
Packaging	Tubing and Needle Sets packaged sterile utilizing an LDPE pouch (P/N 317036), for single patient use.	Tubing and Needle Sets packaged sterile utilizing a nylon pouch (P/N 317050), for single patient use.	Different. Sterile barrier pouch material was updated. The predicate pouch is made of LDPE material while Subject device uses nylon material. The difference in packaging material is supported by packaging performance testing with respect to packaging validation at baseline and shelf-life. The difference in the material do not raise different questions of safety and effectiveness.
Prescription required	Yes	Yes	Same
Intended Population	Adult, Pediatric	Adult, Pediatric	Same
System Accuracy	+/- 8%	Flow rates will fall between the minimum and maximum predicted values as specified in the IFU.	Different The flow rate accuracy between the subject device and predicate device has changed. The flow rate accuracy for K162613 was +/-8%. The subject device provides minimum to maximum flow rate range based on theoretical calculations for each combination of needle and tubing set. A combination of tubing and needle set will not be included in the instructions for use for the viable options for

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FreedomEdge™ Syringe Infusion System (K211206)	Comparison
			patients if the minimum or maximum flow rate is outside of the requirements set forth in the biologic's labeling. The difference in the predicated flow rates for each combination of needle and tubing set do not raise different questions of safety and effectiveness.
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

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)			FreedomEdge™ Syringe Infusion System (K211206)			Comparison
Residual Volumes for HIgH-Flo Needle Sets	Needle	24 G	26 G	Needle	24 G	26 G	Same
	1	0.4 ml	0.1 ml	1	0.4 ml	0.1 ml	
	2	0.7 ml	0.2 ml	2	0.7 ml	0.2 ml	
	3	1.1 ml	0.3 ml	3	1.1 ml	0.3 ml	
	4	1.4 ml	0.4 ml	4	1.4 ml	0.4 ml	
	5	2.0 ml (with Y-connector	0.5 ml	5	2.0 ml (with Y-connector)	0.5 ml	
	6	2.3 ml (with Y-connector)	0.6 ml	6	2.3 ml (with Y-connector)	0.6 ml	
	7	2.7 ml (with Y-connector)	0.9 ml (With Y-connector)	7	2.7 ml (with Y-connector)	0.9 ml (with Y-connector)	
	8	1.0 ml with Y-connector	0.9 ml (With Y-connector)	8	1.0 ml (with Y-connector)	1.0 ml (with Y-connector)	

Table 4. Comparison of HIgH-Flo Super26 needle set and 26G HIgH-Flo needle set

Technological Characteristics	HIgH-Flo™ Subcutaneous Safety Needle Sets (26G) (K162613)	HIgH-FLO Super26™ Subcutaneous Needle Sets (K211206)	Comparison
Tubing Diameter (inches)	0.033 ± 0.002”/0.001”	0.0190 ± 0.001”	Different. With the addition of the Super26, the main difference is the tubing diameter of the Super26 (0.0190 ± 0.001”) which allows for faster flow rates vs. the predicate device. The Super26 is designed and cleared for use with the Subject device under K180843. This difference does not raise different questions of safety and effectiveness and have been verified through performance testing.
Tubing Material	Medical Grade PVC Plastic	Medical Grade PVC Plastic	Same
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Gauge	26	26	Same
Needle Length (mm)	4, 6, 9, 12, 14	4, 6, 9, 12, 14	Same

Technological Characteristics	HIgH-Flo™ Subcutaneous Safety Needle Sets (26G) (K162613)	HIgH-FLO Super26™ Subcutaneous Needle Sets (K211206)	Comparison
Sterilization Method	Gamma	Gamma	Same
Packaging	Tubing and Needle Sets packaged sterile utilizing an LDPE pouch (P/N 317036), for single patient use.	Tubing and Needle Sets packaged sterile utilizing a nylon pouch (P/N 317050), for single patient use.	Different Sterile barrier material is changed from LDPE to a nylon material pouch. Change in packaging material is supporting by non-clinical performance testing and sterilization validation. Packaging is able to maintain sterile barrier of device components. The proposed change is restricted to the pouch material only. No change has been made to the infusion pump system as a result of the change. The difference in packaging material does not affect safety and effectiveness.
Needle Butterfly Wings Material	Polypropylene	Polypropylene with blue colorant (541790C Translucent blue, Marvel Industries, Inc.)	Different The only difference is that blue colorant was added to the needle butterfly wings of the Super26 so the user could easily identify the product. The proposed change is restricted to the needle butterfly wing only. No change has been made to the infusion pump system as a result of the change (addition of blue colorant). This change is considered minor and does not affect safety and effectiveness of the device.

Technological Characteristics	HIgH-Flo™ Subcutaneous Safety Needle Sets (26G) (K162613)		HIgH-FLO Super26™ Subcutaneous Needle Sets (K211206)		Comparison
					Appropriate biocompatibility testing was performed to support use of blue colorant. See Section 16 for full biocompatibility testing.
26 Gauge Needle Set Configurations Available (26 Gauge only)	1 – Needle Set 2 – Needle Set 3 – Needle Set 4 – Needle Set 5 – Needle Set 6 – Needle Set **w/Y-connector** 7 – Needle Set 8 – Needle Set		1 – Needle Set 2 – Needle Set 3 – Needle Set 4 – Needle Set 5 – Needle Set 6 – Needle Set **w/Y-connector** 7 – Needle Set 8 – Needle Set		Same
Residual Volume for the multiple needle configurations	**Needle**	**26 G**	**Needle**	**Super26**	Different. When using a 60 ml dose, the increased residual volume between the HIgH-Flo Super26 and the predicate device (HIgH-Flo Subcutaneous Safety Needle Set) ranges from 0.5% for a 1 leg needle set to 3.3% for an 8-leg needle set (4
	1	0.1 ml	1	0.4 ml	
	2	0.2 ml	2	0.7 ml	
	3	0.3 ml	3	1.1 ml	

Technological Characteristics	HIgH-Flo™ Subcutaneous Safety Needle Sets (26G) (K162613)		HIgH-FLO Super26™ Subcutaneous Needle Sets (K211206)		Comparison
	4	0.4 ml	4	1.4 ml	legs x 2). Residual volumes are stated in the IFU. This change does not raise new questions of safety and effectiveness. Residual volumes are stated in the IFU.
	5	0.5 ml	5	1.8 ml	
	6	0.6 ml	6	2.1 ml	
	7	0.9 ml (With Y-connector)	7	2.7 ml (With Y-connector)	
	8	0.9 ml (With Y-connector)	8	3.0 ml (With Y-connector)	

Discussions of differences in needle sets

The subject device utilizes the same fundamental scientific technology as the predicate device. The Super26 uses a 24G tubing set and a 26G needle. The main difference between Super26 and the 26 gauge HIgH-Flo Subcutaneous Needle Set is the tubing diameter of the Super26, which provides greater flexibility for the patient to use higher viscosity medications during infusion per the drug manufacturer's recommended limits. The diameter of the tubing used in the subject device (HlgH-FloSuper26™ Sub-Q Needle Sets) with 26G needles is 0.033 inches, which is different from the predicate's 0.019 inches.

Also, the Super26 uses a Y connector with 7 and 8 legs while the 24G uses a Y connector with 5, 6, 7 and 8 Legs. The Y connector has ~.2 mL residual volume. Bench testing was conducted in K180843 to verify that the product performance of the subject device and predicate device are substantially equivalent. Any differences between HIgH-Flo Super26 needle set and 26G HIgH-Flo needle set do not raise different questions of safety and effectiveness.

As shown in the predicate device comparison chart in **Table 4**, HIgH-Flo Super26™ Subcutaneous Needle Sets have the same technological characteristics as the predicate device.

The HIgH-Flo Super26™ Subcutaneous Needle Sets are considered as substantially equivalent to the legally marketed predicate device, i.e., K162613 and demonstrated to be as safe and effective as legally marketed devices.

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 only changes introduced in this 510(k) do not impact the associated risks or reliability in the Safety Assurance Case as compared to the predicate. Therefore only evidence to support changes to the device requirements to ensure adequate verification and validation were needed to support substantial equivalence.

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, in accordance with the following tables:

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 (+/- 15%).

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 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.