Repro-Med Systems, Inc., dba KORU Medical Systems
Kachi Enyinna
Vice President of Global Commercialization
24 Carpenter Road
Chester, New York 10918

December 15, 2021

Re: K200176
Trade/Device Name: FREEDOM Integrated Syringe Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, FPA, PKP
Dated: March 30, 2021
Received: March 30, 2021

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)*
K200176

Device Name
FREEDOM® Integrated Syringe Infusion System

Indications for Use *(Describe)*

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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); 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 Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.

The FREEDOM Integrated Syringe Infusion System with the FREEDOM60® 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 Freedom Integrated Syringe Infusion System consists of the following components:

- FREEDOM60® 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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®).

The FREEDOM60® Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
K200176

I. SUBMITTER

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Date Prepared: November 12, 2021

II. DEVICE

Name of Device: FREEDOM® Integrated 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
This predicate has not been subject to a design-related recall.

Reference Device: KORU HIgH-Flo Super26™ Subcutaneous Safety Needle Set, K180843.
This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The FREEDOM® Integrated Syringe Infusion System is a single-channel, volumetric infusion pump. The FREEDOM60® Integrated Syringe Infusion System consists of four primary components:

1. FREEDOM60® 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. FREEDOM60® Syringe Driver:

The FREEDOM60® Syringe Driver in combination with Precision Flow Rate Tubing™ (sterile) and HIgH-Flo Subcutaneous Safety Needle Sets (sterile) makes up the Freedom Integrated Syringe Infusion system. The FREEDOM60® Syringe Driver is a non- sterile, reusable non-electric driver that infuses immunoglobulins subcutaneously and antibiotic solutions intravenously to patients.

The FREEDOM60® Syringe Driver is an ambulatory device designed to accommodate a BD Luer- Lok™ 50mL Syringe (Catalog No.: 8881-560125, BD 309653), and fluid volumes ranging from 10cc to 60cc may be used. The pump uses a constant force spring mechanism to apply pressure to the plunger-end syringe.

The Freedom Integrated Syringe 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.

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. 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 (FREEDOM60®) 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 two new drugs, Xembify and Cutaquig, 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 FREEDOM® Integrated 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 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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); 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 Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The Freedom Integrated Syringe Infusion System with the FREEDOM60® 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 Freedom Integrated Syringe Infusion System consists of the following components:

- FREEDOM60® 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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution

(manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®).

The FREEDOM60® Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 309653).

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 (K200176)** FREEDOM® Integrated 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: meropenem, ertapenem, oxacillin, and tobramycin. The FreedomEdge® Syringe Infusion System is indicated for use with the BD 20 ml (model no.	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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); 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 Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. The Freedom Integrated Syringe Infusion System with the FREEDOM60® 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 Freedom Integrated Syringe Infusion System

	Predicate Device (K162613) Integrated Catch-Up FREEDOM Syringe Driver Infusion System	**Subject Device (K200176)** FREEDOM® Integrated Syringe Infusion System
	Current configuration	**New configuration**
	Current Indications for Use as cleared August 31, 2017	**Modified Indications for Use**
	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).	consists of the following components: • FREEDOM60® 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: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®). The FREEDOM60® Syringe Driver is indicated for use with the BD® 50 ml syringe (US Reference number 309653).
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 FREEDOM® Integrated Syringe Infusion System is not identical to the predicate device. The submission expands on the currently cleared indications for use to include the addition of two new drugs, Xembify and Cutaquig, and the HIgH-Flo Super26™ Subcutaneous Needle Set to the infusion system. The difference between the subject device and predicate device infusion systems are the inclusion of the of two new drugs, Xembify and Cutaquig and the HIgH-Flo Super 26™ Subcutaneous Needle Set into the indications for use.

Compatibility of Xembify and Cutaquig and HIgH-Flo Super26™ with the FREEDOM60® Integrated Syringe Infusion System specifically, has been verified through performance testing. The FREEDOM® Integrated 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 FREEDOM60® 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** **K200176** FREEDOM® Integrated 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 FREEDOM60® 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, FREEDOM® Integrated Syringe Infusion System. The main difference is that the subject device is re-configured and packaged with only one syringe driver (FREEDOM60® 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 flow rates between 24 gauge and 26 gauge needle sets. Both needle sets are intended for the delivery of medication to the subcutaneous tissue. The HIgH-Flo Super26™ is cleared for use with the FREEDOM60® 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, predicate device, and reference 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)**	**FREEDOM Integrated Syringe Infusion System** **(K200176)**	**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	FREEDOM60® Syringe Driver: Manual knob used to tension negator constant force spring	Same winding of spring for FREEDOM60®.
On / Off Control	Manual switch	Manual switch	Same
Housing	Molded ABS	Molded ABS	Same
Syringe Type	FREEDOM60® BD 50 mL syringe (model no. 309653) 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)	Same

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FREEDOM Integrated Syringe Infusion System (K200176)	Comparison
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
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

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FREEDOM Integrated Syringe Infusion System (K200176)	Comparison
			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 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

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)	FREEDOM Integrated Syringe Infusion System (K200176)	Comparison
			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
Residual Volumes for HIgH-Flo Needle Sets	Needle: 1 / 24 G: 0.4 ml / 26 G: 0.1 ml Needle: 2 / 24 G: 0.7 ml / 26 G: 0.2 ml	Needle: 1 / 24 G: 0.4 ml / 26 G: 0.1 ml Needle: 2 / 24 G: 0.7 ml / 26 G: 0.2 ml	Same

Technological Characteristics	Integrated Catch-up FREEDOM Syringe Driver Infusion System (ICSDIS, known as Freedom Infusion System) (K162613)			FREEDOM Integrated Syringe Infusion System (K200176)			Comparison
	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)** **(predicate)**	**HIgH-FLO Super26™ Subcutaneous Needle Sets** **(reference)**	**Comparison**
Tubing Diameter (inches)	0.0190 ± 0.001”	0.033 ± 0.002”/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) (predicate)	HIgH-FLO Super26™ Subcutaneous Needle Sets (reference)	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.

<table>
<tr><th>Technological Characteristics</th><th colspan="2">HIgH-Flo™ Subcutaneous Safety Needle Sets (26G)
(predicate)</th><th colspan="2">HIgH-FLO Super26™ Subcutaneous Needle Sets
(reference)</th><th>Comparison</th></tr>
<tr><td></td><td colspan="2"></td><td colspan="2"></td><td>Appropriate biocompatibility testing was performed to support use of blue colorant. See Section 16 for full biocompatibility testing.</td></tr>
<tr><td>26 Gauge Needle Set Configurations Available (26 Gauge only)</td><td colspan="2">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</td><td colspan="2">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</td><td>Same</td></tr>
<tr><td rowspan="4">Residual Volume for the multiple needle configurations</td><td>Needle</td><td>26 G</td><td>Needle</td><td>Super26</td><td rowspan="4">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</td></tr>
<tr><td>1</td><td>0.1 ml</td><td>1</td><td>0.4 ml</td></tr>
<tr><td>2</td><td>0.2 ml</td><td>2</td><td>0.7 ml</td></tr>
<tr><td>3</td><td>0.3 ml</td><td>3</td><td>1.1 ml</td></tr>
</table>

Technological Characteristics	HIgH-Flo™ Subcutaneous Safety Needle Sets (26G) (predicate)		HIgH-FLO Super26™ Subcutaneous Needle Sets (reference)		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 reference 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 who 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 FREEDOM60® Integrated 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 FREEDOM60® Integrated 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 FREEDOM60® Integrated 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 FREEDOM60® Integrated 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 FREEDOM60® Integrated 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 Cutaquig®, Xembify®, Gammagard® Liquid, Hizentra® PI, and Hizentra® CIPD.

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

Cutaquig® 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 FREEDOM60® Integrated Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Cutaquig.

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	6.6 – 13.5	9 – 16.2	12.3 – 22.3						
2 needles	3.5 – 7.5	5 – 9.1	7.1-13.2	9.5-19.1	11.8-20.6	13.1 – 23.7			
3 needles	2.4 -5.2	3.5-6.3	5 -9.4	6.8 -14	8.6 -15.2	9.7-17.8	13.8 -24.9		
4 needles	1.8 -3.9	2.7-4.9	3.9-7.3	5.3 -11	6.8 -12	7.7-14.2	11.3 -20.5	12.4 -24.4	
5 needles	1.5 -3.2	2.2-3.9	3.2- 6	4.3 -9.1	5.6 -10	6.4 -11.8	9.5 -17.4	10.5 -20.9	
6 needles	1.2-2.7	1.8-3.3	2.7-5	3.7-7.7	4.8 - 8.5	5.4 -10.1	8.2-15.1	9.1 -18.3	

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

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

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	7.1 -15	10.1 -18.3							
2 needles	3.7-7.9	5.3 -9.7	7.8 -14.6	10.6 -22.1	13.7-24.2				
3 needles	2.5 -5.4	3.6 - 6.6	5.3 -10.1	7.4 -15.5	9.6 -17.1	10.9-20.3			
4 needles	1.9- 4.1	2.8 -5	4.1 -7.7	5.7-12	7.4 -13.2	8.4 -15.8	13 -24		
5 needles	1.5 -3.3	2.2- 4.1	3.3- 6.2	4.6 -9.7	6 -10.7	6.9-12.9	10.7-19.8	12-24.6	
6 needles	1.3 -2.7	1.9-3.4	2.7-5.2	3.8- 8.2	5.1 -9.1	5.8 -10.9	9.1 -16.9	10.2-21.1	

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	7.4 -15.9	10.8 -19.7							
2 needles	3.8 - 8.1	5.5 -10.1	8.2-15.5	11.4 -24.2					
3 needles	2.5 -5.5	3.7- 6.8	5.5 -10.5	7.7-16.5	10.2-18.3	11.7-22.1			
4 needles	1.9- 4.1	2.8 -5.1	4.2-7.9	5.9-12.6	7.8 -13.9	8.9-16.8			
5 needles	1.5 -3.3	2.2- 4.1	3.3- 6.4	4.7-10.1	6.3 -11.2	7.2-13.6	11.4 -21.5		
6 needles	1.3 -2.8	1.9-3.4	2.8 -5.3	3.9- 8.5	5.2-9.4	6 -11.4	9.6 -18.1	10.9-22.9	

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 6th infusion only.

Xembify® 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 FREEDOM60® Integrated Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Xembify.

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 <u>26G</u> with Precision Tubing – Min-Max Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	3.7-9.4	5 -11.2	6.9-15.5	8.7-20.9	10.4 -22.2	11.3 -24.7			
2 needles	2-5.2	2.8 - 6.3	4 -9.2	5.3 -13.3	6.6 -14.3	7.3 -16.4	10 -22.1		
3 needles	1.4 -3.6	1.9- 4.4	2.8 - 6.5	3.8 -9.7	4.8 -10.5	5.4 -12.3	7.7-17.3	8.4 -20.2	
4 needles	1 -2.7	1.5 -3.4	2.2-5.1	3 -7.6	3.8 - 8.4	4.3 -9.8	6.3 -14.2	6.9-16.9	
5 needles	0.8 -2.2	1.2-2.7	1.8 - 4.1	2.4 - 6.3	3.1- 6.9	3.5- 8.2	5.3 -12.1	5.9-14.5	9.4 -23.3
6 needles	0.7-1.9	1 -2.3	1.5 -3.5	2.1 -5.4	2.7-5.9	3 -7	4.6 -10.5	5.1 -12.7	8.4 -21.1

Exceeds drug manufacturer's maximum indicated flow rate.

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

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	4.2-11	6 -13.6	8.8 -20.5						
2 needles	2.1 -5.6	3.1 -7	4.6 -10.7	6.4 -16.8	8.4 -18.5	9.5 -22.2			
3 needles	1.4 -3.8	2.1 - 4.7	3.1 -7.3	4.3 -11.5	5.7-12.7	6.5 -15.3	10.3 -23.8		
4 needles	1.1 -2.9	1.6 -3.6	2.3 -5.5	3.3 - 8.7	4.3 -9.6	5 -11.7	7.9-18.3	8.9-23.1	
5 needles	0.9-2.3	1.3 -2.9	1.9- 4.4	2.6 -7	3.5 -7.8	4 -9.4	6.4 -14.9	7.2-18.8	
6 needles	0.7-1.9	1 -2.4	1.6 -3.7	2.2-5.9	2.9- 6.5	3.4 -7.9	5.4 -12.6	6.1 -15.9	

Exceeds drug manufacturer's maximum indicated flow rate.

Cuvitru® PI Flow Rate Combinations

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (Standard 26G, 24G and Super26™) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Integrated Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Cuvitru (±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 <u>26G</u> with Precision Tubing – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle		10.4	14.0	18.5	21.0	22.7	27.3	28.6	35.3
2 needles				12.0	14.1	15.7	20.4	21.9	31.0
3 needles					10.6	12.0	16.3	17.7	27.6
4 needles							13.6	14.9	24.8

Outside of drug manufacturer's indicated flow rate (min/max)

Subsequent infusions after 6th infusion only.

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

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle		12.0	17.0	24.1	28.5	31.6	41.2	44.3	
2 needles				14.0	17.1	19.4	27.3	30.1	50.4
3 needles					12.3	14.0	20.4	22.8	42.0
4 needles						11.0	16.3	18.3	36.0

Outside of drug manufacturer's indicated flow rate (min/max)

Subsequent infusions after 6th infusion only.

HIgH-Flo <u>24G</u> with Precision Tubing – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	10.0	13.1	19.3	28.9	35.5	40.5	57.8		
2 needles			10.1	15.6	19.5	22.5	33.7	38.1	
3 needles				10.7	13.4	15.6	23.8	27.1	59.3
4 needles					10.2	11.9	18.4	21.0	48.0

Outside of drug manufacturer's indicated flow rate (min/max)

Subsequent infusions after 6th infusion only.

Gammagard Liquid® Selected Flow Rate Combinations

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (Standard 26G and 24G) when used in combi- nation with KORU Precision Flow Rate Tubing™ and FREEDOM60® Integrated Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Gammagard Liquid (±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.

40 kg and greater BW

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

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle									
2 needles	22.4	28.6							
3 needles	15.5	20.1	29.1						
4 needles	11.9	15.4	22.6						
5 needle	9.6	12.5	18.5	27.8					
6 needles	8.1	10.6	15.7	23.7	29.3				
7 needles	7.0	9.1	13.6	20.7	25.7	29.5			
8 needles	6.1	8.0	12.0	18.4	22.8	26.3			

Exceeds drug manufacturer's maximum indicated flow rate

Subsequent infusions after 6th infusion only.

Under 40 kg BW

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

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle									
2 needles									
3 needles	15.5	20.1							
4 needles	11.9	15.4							
5 needle	9.6	12.5	18.5						
6 needles	8.1	10.6	15.7						
7 needles	7.0	9.1	13.6						
8 needles	6.1	8.0	12.0	18.4					

Exceeds drug manufacturer's maximum indicated flow rate

Subsequent infusions after 6th infusion only.

Hizentra® PI Flow Rate Combinations

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (Standard 26G, 24G and Super26™) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Integrated Syringe Infusion System with a 50 ml syringe for the subcutaneous use of Hizentra PI (±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 – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	8.2	10.2	13.7	18.1	20.6	22.2			
2 needles	4.6	5.8	8.3	11.7	13.8	15.3	20.0	21.4	
3 needles	3.2	4.1	5.9	8.6	10.4	11.7	16.0	17.4	
4 needles	2.4	3.1	4.6	6.9	8.4	9.5	13.3	14.6	24.3
5 needle	2.0	2.6	3.8	5.7	7.0	8.0	11.4	12.6	22.2
6 needles	1.6	2.2	3.2	4.8	6.0	6.9	9.9	11.1	20.3
7 needles	1.4	1.9	2.8	4.2	5.2	6.0	8.8	9.9	18.8
8 needles	1.2	1.6	2.4	3.7	4.7	5.4	8.0	8.9	17.4

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	9.2	11.7	16.6	23.6					
2 needles	4.8	6.3	9.3	13.8	16.8	19.0			
3 needles	3.3	4.3	6.4	9.7	12.0	13.8	20.0	22.3	
4 needles	2.5	3.3	4.9	7.5	9.3	10.8	16.0	17.9	
5 needle	2.0	2.6	4.0	6.1	7.7	8.8	13.3	15.0	
6 needles	1.7	2.2	3.3	5.2	6.5	7.5	11.4	12.9	
7 needles	1.4	1.9	2.9	4.5	5.6	6.5	10.0	11.3	24.7
8 needles	1.3	1.7	2.5	3.9	5.0	5.8	8.8	10.1	22.4

Exceeds drug manufacturer's maximum indicated flow rate

Subsequent infusions after 6th infusion only.

HIgH-Flo <u>24G</u> with Precision Tubing – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	9.8	12.8	18.9						
2 needles	5.0	6.6	9.9	15.2	19.1	22.0			
3 needles	3.4	4.5	6.7	10.4	13.1	15.2	23.3		
4 needles	2.5	3.4	5.1	7.9	10.0	11.7	18.0	20.6	
5 needle	2.0	2.7	4.1	6.4	8.1	9.4	14.7	16.8	
6 needles	1.7	2.3	3.4	5.4	6.8	7.9	12.4	14.2	
7 needles	1.5	1.9	2.9	4.6	5.8	6.8	10.7	12.3	
8 needles	1.3	1.7	2.6	4.0	5.1	6.0	9.4	10.8	

Exceeds drug manufacturer's maximum indicated flow rate

Subsequent infusions after 6th infusion only.

Hizentra® CIDP Selected Flow Rate Combinations

The following tables indicate the nominal predicted flow rates per site with HIgH-Flo Subcutaneous Safety Needle Sets™ (Standard 26G, 24G and Super26™) when used in combination with KORU Precision Flow Rate Tubing™ and FREEDOM60® Integrated Syringe Infusion System with a 50 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 – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	8.2	10.2	13.7	18.1	20.6	20.6	26.7	28.0	34.6
2 needles	4.6	5.8	8.3	11.7	13.8	15.3	20.0	20.0	30.3
3 needles	3.2	4.1	5.9	8.6	10.4	11.7	16.0	17.4	27.0
4 needles	2.4	3.1	4.6	6.9	8.4	9.5	13.3	14.6	24.3
5 needle	2.0	2.6	3.8	5.7	7.0	8.0	11.4	12.6	22.2
6 needles	1.6	2.2	3.2	4.8	6.0	6.9	9.9	11.1	20.3
7 needles	1.4	1.9	2.8	4.2	5.2	6.0	8.8	9.9	18.8
8 needles	1.2	1.6	2.4	3.7	4.7	5.4	8.0	8.9	17.4

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	9.2	11.7	16.6	23.6	27.9	30.9	40.4	43.4	
2 needles	4.8	6.3	9.3	13.8	16.8	19.0	26.8	29.5	49.3
3 needles	3.3	4.3	6.4	9.7	12.0	13.8	20.0	22.3	41.1
4 needles	2.5	3.3	4.9	7.5	9.3	10.8	16.0	17.9	35.2
5 needle	2.0	2.6	4.0	6.1	7.7	8.8	13.3	15.0	30.8
6 needles	1.7	2.2	3.3	5.2	6.5	7.5	11.4	12.9	27.4
7 needles	1.4	1.9	2.9	4.5	5.6	6.5	10.0	11.3	24.7
8 needles	1.3	1.7	2.5	3.9	5.0	5.8	8.8	10.1	22.4

Exceeds drug manufacturer's maximum indicated flow rate

Subsequent infusions after 6th infusion only.

HIgH-Flo <u>24G</u> with Precision Tubing – Nominal Flow Rate Per Site (ml/hr/site)

	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	9.8	12.8	18.9	28.3	34.8	39.7			
2 needles	5.0	6.6	9.9	15.2	19.1	22.0	33.0	37.3	
3 needles	3.4	4.5	6.7	10.4	13.1	15.2	23.3	26.5	
4 needles	2.5	3.4	5.1	7.9	10.0	11.7	18.0	20.6	47.0
5 needle	2.0	2.7	4.1	6.4	8.1	9.4	14.7	16.8	39.5
6 needles	1.7	2.3	3.4	5.4	6.8	7.9	12.4	14.2	34.0
7 needles	1.5	1.9	2.9	4.6	5.8	6.8	10.7	12.3	29.9
8 needles	1.3	1.7	2.6	4.0	5.1	6.0	9.4	10.8	26.7

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 FREEDOM60® Integrated 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 FREEDOM60® 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, predicate device and reference device do not raise different questions of safety or effectiveness. Based on performance testing results, the FREEDOM60® Integrated Syringe Infusion System, performs as intended and performs comparably to the predicate device that is currently marketed for the same intended use.