510(k) Summary

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General Information
Classification: Class II
Trade Name: Integrated Catch-Up Freedom Syringe Driver Infusion System
Common Name: Infusion Pump

Regulation Number: 21 CFR §880.5725

Product Codes:
PKP, Immunoglobulin G (Igg) Infusion System
FRN, Infusion Pump
FPA, Intravascular Administration Set

Indications for Use

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. 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).

Primary Predicate Device
K933652, Freedom60 Syringe Infusion System

Reference Device(s)
K161906, SCIg60 Infusion System
K102512, RMS Subcutaneous Needle Set
K122404, RMS High-Flow Subcutaneous Safety Needle Sets

Comparison of Indications for Use of Subject and Predicate Devices

The Integrated Catch-Up Freedom Syringe Driver Infusion System and the Subcutaneous Infusion Set predicate are both intended for the subcutaneous infusion of medicines such as immunoglobulins using RMS Precision Flow Rate Tubing Sets and High-Flo Needle Sets. In addition, the Integrated Catch-Up Freedom Syringe Infusion System is also intended to deliver intravenous medications such as antibiotics. For subcutaneous immunoglobulin G infusion, the subject device is intended specifically for subcutaneous infusion of Hizentra, Cuvitru, and Gammagard Liquid from the BD 60 ml syringe, similar to the reference device. The subject device is also able to deliver a variety of drug concentrations and parenteral fluids such as antibiotics. These indications for use fall into the general intended use of the predicate device as an infusion pump. The intended use of the FreedomEdge® Syringe Infusion System and the FREEDOM60® Syringe Infusion System are identical except for the fact that the FreedomEdge Syringe Infusion System utilizes 20 ml or 30 ml syringes while the Freedom60 Syringe Infusion System utilizes a 60 ml syringe. Both syringe drivers incorporate equivalent design and the same principle of action as the primary predicate device in order to provide controlled flow of liquid medications at a constant pressure with adjustable flow rates, operating for intravenous and subcutaneous infusion therapies.

Device Description:

1. Freedom60® Syringe Driver: The Freedom60 Syringe Infusion driver in combination with RMS Freedom60 Precision Flow Rate Tubing™ (sterile) and RMS HIgH-Flo Subcutaneous Safety Needle Sets (sterile) makes up the Freedom60 infusion system. The Freedom60® driver is a non-sterile, reusable non-electric driver that infuses immunoglobulins subcutaneously and antibiotic solutions intravenously to patients.

   The Freedom60® driver is an ambulatory device designed to accommodate a BD Luer-Lok™ 60mL 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 Freedom60 system is assembled by loading the prefilled syringe with tubing into the Freemdom60 driver.

2. FreedomEdge® Syringe Driver: The FreedomEdge® Syringe Infusion driver is used with a syringe in an infusion system for administering therapeutic fluids. The infusion system or related kits can include, in addition to the pump assembly, a luer connector or disc luer connector for connecting the syringe to components of the infusion system, an RMS Precision Flow Rate Tubing™ (sterile) and RMS HIgH-Flo Subcutaneous Safety Needle Sets (sterile) for administering the therapeutic fluid subcutaneously into a patient's body.

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

The FreedomEdge® is comprised of housing that has a distal end and a proximal end. The housing comprises an expandable base with a first base section and a second base section, wherein the first base section is in sliding engagement with the second base section such that the first base section and the second base section move relative to each other between a closed position and an expanded position. The base in the expanded position is adapted to seat a syringe with the plunger.

There is also an expandable cover consisting of a first cover section and a second cover section, wherein the first cover section is in sliding engagement with the second cover section. The cover is pivotally connected to the base at a position allowing the cover to open and close in a sliding motion of the second base section, which is relative to the first base section moving together.

When the cover is in the closed position, a pusher is in sliding engagement with the base. The pusher is in position to contact the head of the plunger and a puller is in position with the sliding engagement of the base. There is a spring at the first end portion and a second end portion. The first end portion is connected to the puller, while the second end portion is connected to the pusher and a set of linkages pivotally coupled to the cover and the puller.

The pivots of the linkages are located to move the puller towards the distal end when the cover is lowered and move the puller towards the proximal end when the cover is raised. Moving the puller towards the distal end by lowering the cover when the syringe is seated in the base causes the pusher to contact and exert force on the head of the plunger, thereby causing ejection of any fluid contents in the syringe barrel.

3. Precision Flow Rate Tubing Set:

   The Freedom60 Infusion system includes a range of Freedom Precision Flow Rate Tubing™. 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.

4. High-Flo Needles set: The HIgH-Flo™ Subcutaneous Safety Needle Sets are used to administer drugs to the subcutaneous layers using small needles attached to the skin. Typical uses are to administer immunoglobulins and antibiotics and for such applications subcutaneous needles come in different lengths.

   Subcutaneous Safety Needle Sets comes in multiple configurations (single, double, tri, and quad). 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 trapped between the wings after use.

Technological Characteristics

The Freedom60® Syringe Driver is portable, requiring no batteries or electricity. There are only two operating knobs and dedicated tubing sets are used to control the flow rate. The Freedom60 operates at a constant pressure of 13.5psi. The constant pressure developed in the Freedom60 automatically decreases the flow rate if there is an increase in resistance during the delivery. The

system will find equilibrium between the increasing resistance and the flow rate. The FREEDOM60® is designed for 60ml syringes.

The FreedomEdge® Syringe Driver is portable, requiring no batteries or electricity. It starts to operate when the pump is closed. RMS Precision Flow Rate Tubing™ sets are used to control the flow rate. The FreedomEdge® operates at a constant pressure of 13.5psi. The constant pressure developed in the FreedomEdge® automatically decreases the flow rate if there is an increase in resistance during the delivery. The system will find equilibrium between the increasing resistance and the flow rate. The FreedomEdge® has all the same technical characteristics of the FREEDOM60®, in a design for 20ml and 30ml syringes.

RMS Precision Flow Rate Tubing™ controls the infusion rate within the Integrated Catch-Up Freedom Syringe Infusion System. 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.

HIgH-Flo needles were designed specifically to work with RMS Precision Flow Rate Tubing™ and a Freedom Syringe Driver as a total infusion system with multiple infusion options. It uses a specific backcut needle tip design. It has a flexible flying hinge and a custom luer designed to provide even flow to every site. Set options are available in single (1), double (2), triple (3), and quad (4) configurations. Using the Y-Connector, the patient can have up to 8 sites for drug delivery. Needles are available in 4mm, 6mm, 9mm, 12mm, and 14mm in lengths.

Performance Testing

A safety assurance case for the Integrated Catch-Up Freedom Syringe Infusion System covered by design-FMEA (Failure Mode Effects Analysis) and use-FMEA was provided following the FDA guidance document, Infusion Pumps Total Product Life Cycle (2014). Based on the FMEA documents, the safety assurance case has demonstrated that Integrated Catch-Up Freedom Syringe Infusion System is safe for its intended use. In addition, it also demonstrated the safety assurance case includes:

1. Device design is verified and validated
2. Risks (failure mode) associated with the Device are completely identified and properly controlled and mitigated to cover, but not limited the risks related to:
    a. Operation
    b. Hardware/mechanical
    c. Use/performance
    d. Environment/chemical
    e. Different level of errors

Drug-device compatibility testing was conducted using validated test methods and results showed acceptable for immunoglobulins, Hizentra and Cuvitru, with the Freedom System to evaluate characters of:

- Appearance;
- Particulates;
- Protein concentration;
- Amount of IgG fragments, polymers or aggregates;
- Anti-complementary activity (ACA);

- Density; and,
- Fc-function

The detailed flow rate testing were conducted for all immunoglobulins including Hizentra (20%), Cuvitru (20%), and Gammagard Liquid (10%), using Freedom60, FreedomEdge, RMS Precision Flow Rate Tubing and RMS High-Flo Needles. The flow rate profiles per each testing are listed below to present subcutaneous administration set combinations in order to achieve desired infusion rates for each of the indicated immunoglobulin fluids, in accordance with the following tables:

The Tables Below Represent Select Combinations of Flow Rates and Needles Sets for Use with Hizentra, Cuvitru, and Gammagard Liquid.

***Note that the following tables are only for the subcutaneous use of the immunoglobulin listed.**

Table 1. Hizentra – Driver is FREEDOM60® or FreedomEdge® with 20ml ml syringe

Drug volume (ml)	Flow Tube	High Flo Set	Flow Rate Total (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
10	F120	RMS 1-2609	8.2	8.2	10	1:12	Suggested start Peds
10	F180	RMS 1-2609	10.5	10.5	10	0:57	Suggested start Peds
20	F275	RMS 2-2609	17.1	8.5	10	1:10	Suggested start Peds
20	F600	RMS 2-2609	29.6	14.8	10	0:40	Suggested start Peds
40	F600	RMS 3-2609	33.9	11.3	13.3	1:10	Suggested start Adult
40	F900	RMS 3-2609	44.3	14.8	13.3	0:54	Suggested start Adult
60	F900	RMS 4-2609	49.0	12.3	15	1:13	Suggested start Adult
50	F2400	RMS 3-2609	72.2	24.1	16.7	0:41	6th Infusion of biologic and beyond
100	F2400	RMS 4-2609	85.5	21.4	25	1:10	6th Infusion of biologic and beyond (NEEDS TWO SYRINGES)

Table 2. Hizentra – Driver is FreedomEdge® with 30ml syringe

Drug volume (ml)	Flow Tube	High Flo Set	Flow Rate total (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
20	F600	RMS 2-2609	22.5	11.2	10	0:53	Suggested start Peds
30	F900	RMS 2-2609	28.3	14.2	15	1:03	Suggested start Adult
30	F2400	RMS 2-2609	41.9	20.9	15	0:42	6th Infusion of biologic and beyond

NOTE: 1. Based on combining elements as written in Theory and Measurement of Fluid Flow Rates in the Freedom system. Other combinations available per request

NOTE: 2. 24 G Needles are not needed for performance up to 24.08 mL/hr for Hizentra

Table 3. Cuvitru - Driver is FREEDOM60® or FreedomEdge® with 20ml syringe

Drug volume (ml)	Flow Tube	High Flo Set	Flow Rate Total (ml/hr)	Flow rate/site (ml/hr)	Vol/site (ml)	Time	NOTES:
10	F275	RMS 1-2609	12.1	12.1	10	0:49	1st Two Infusions patients under 40kg
20	F275	RMS 1-2609	12.1	12.1	20	1:39	1st Two Infusions patients under 40kg
20	F600	RMS 2-2609	25.7	12.8	10	0:47	1st Two Infusions patients under 40kg

50	F600	RMS 2-2609	25.7	12.8	25	1:57	1st Two Infusions patients over 40kg
60	F1200	RMS 2-2609	37.1	18.6	30	1:37	Subsequent Infusions
60	F2400	RMS 2-2409*	110.5	55.4	30	0:32	Subsequent Infusions
60	F1200	RMS 1-2409*	55.3	55.3	60	1:05	Subsequent Infusions
100	F2400	RMS 4-2409*	132.8	33.2	25	0:45	Subsequent Infusions

*Indicates 24 gauge needle was used.

Table 4. Cuvitru - Driver is FreedomEdge® with 30ml syringe

Drug volume (ml)	**Flow Tube**	**High Flo Set**	**Flow Rate total (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
20	F500	RMS 1-2609	12.9	12.9	20	1:32	1ST Two Infusions patients under 40kg
30	F900	RMS 2-2609	24.6	12.3	15	1:13	1st Two Infusions patients over 40kg
30	F2400	RMS 1-2609	21.2	21.2	30	1:24	Maintenance Infusions
30	F1200	RMS 1-2409*	42.1	42.1	30	0:42	Maintenance Infusions

*Indicates 24 gauge needle was used.

Table 5. Gammagard Liquid with FREEDOM60® or FreedomEdge® with 20ml syringe

Drug volume (ml)	**Flow Tube**	**High Flo Set**	**Flow Rate Total (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
20	F45	RMS 1-2609	14.2	14.2	20	1:24	Patients under 40kg (Initial)
60	F120	RMS 2-2609	39.8	19.9	30	1:30	Patients over 40kg (Initial)

100	F420	RMS 4-2609	119.1	29.8	25	0:50	Patients over 40kg (maintenance infusions)

Table 6. Gammagard Liquid: Driver is FreedomEdge® with 30ml syringe

Drug volume (ml)	**Flow Tube**	**High Flo Set**	**Flow Rate Total (ml/hr)**	**Flow rate/site (ml/hr)**	**Vol/site (ml)**	**Time**	**NOTES:**
20	F120	RMS 2-2609	30	15	10	0:40	Patients under 40kg(Initial)
30	F180	RMS 2-2609	39.8	19.9	15	0:45	Patients over 40kg (Initial)
30	F120	RMS 1-2609	27.0	27.0	30	1:06	Patients over 40kg (Maintenance)