



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 31, 2017

Repro-med Systems, Inc., DBA RMS Medical Products
Fred Ma, M.D., Ph.D.
Chief Medical Officer
24 Carpenter Road
Chester, New York 10918

Re: K162613

Trade/Device Name: Integrated Catch-up Freedom Syringe Driver Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, PKP, FPA
Dated: July 27, 2017
Received: July 31, 2017

Dear Dr. Ma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162613

Device Name

Integrated Catch-Up Freedom Syringe Driver Infusion System

Indications for Use (Describe)

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).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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

510(k) Number: K162613

Summary Prepared: August 31, 2017

Submitter: Dr. Fred Ma
Repro Med System, Inc., D/B/A RMS Medical Products 24
Carpenter Road,
Chester, NY 10918
Tel: 845-469-2042
Fax: 845-469-5518

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 Freedom60 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	6 th Infusion of biologic and beyond
100	F2400	RMS 4-2609	85.5	21.4	25	1:10	6 th 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	6 th 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	1 st Two Infusions patients under 40kg
20	F275	RMS 1-2609	12.1	12.1	20	1:39	1 st Two Infusions patients under 40kg
20	F600	RMS 2-2609	25.7	12.8	10	0:47	1 st Two Infusions patients under 40kg

50	F600	RMS 2-2609	25.7	12.8	25	1:57	1 st 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	1 ST Two Infusions patients under 40kg
30	F900	RMS 2-2609	24.6	12.3	15	1:13	1 st 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)