K180843 510(k) Summary

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Device Name:
Trade Name: RMS HlgH-Flo Super26™ Subcutaneous Needle Set
Common Name: Intravascular Administration Set
Classification: Class II device, 21 CFR §880.5440
Product Code: FPA

Legally marketed predicate device to which substantial equivalence is claimed:
(K162613) Integrated Catch-up Freedom Syringe Driver Infusion System

Device Description:
The RMS HlgH-Flo Super26™ Subcutaneous Needle Sets are sterile, non-pyrogenic, single use, Class II Subcutaneous Administration Set, per 21 CFR 880.5440, 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 (Figure I). Additionally, each tubing set is equipped with a slide clamp used to stop flow, immediately; as needed. RMS HlgH-Flo Super 26™ Subcutaneous Needle Sets are available as a single-needle 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 device is for single use only.

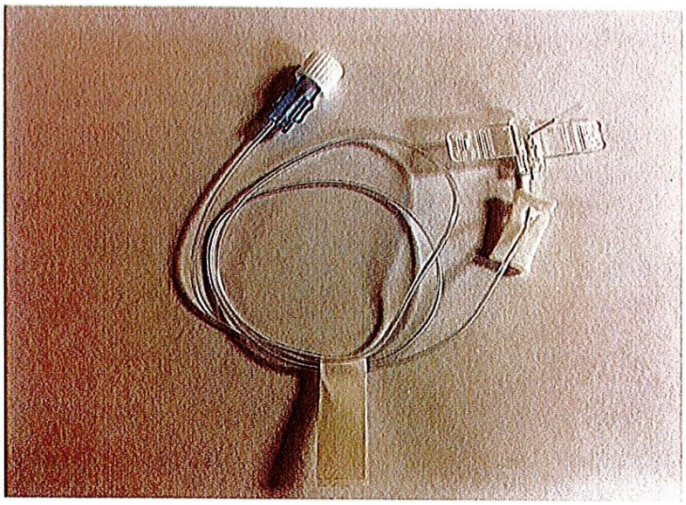

Figure I.

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Indications for Use:
RMS High-FLO Super26™ Subcutaneous Needle Sets are indicated for subcutaneous infusion of medications in the home, hospital, or ambulatory settings, when administered according to the approved biologic or drug product labeling for the capacity for infusion of high flow rates including human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling; for: Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring); and Cuvitru™ Immune Globulin Infusion (Human) 20% (manufactured by Shire).

Comparison to Predicate Device:
The subject device utilizes the same fundamental scientific technology as the predicate device. The purpose for this submission is to introduce a design modification/combination of the needle gauge and tubing diameter. Bench testing has been conducted to verify that the product performance of the subject device and predicate device are substantially equivalent. The table below gives a comparison of both devices.

Feature	**Subject Device:** HlgH-FloSuper26™ Sub-Q Needle Sets	**Predicate Device:** Integrated Freedom Syringe Driver Infusion System
510(k) Number	K180843	K162613
Manufacturer	Same as Predicate	Repro Med Systems, Inc., dba RMS Medical Products
Product Code	Same as Predicate	FPA
Regulation Number	Same as Predicate	880.5440
Regulation Name	Same as Predicate	Intravascular Administration Set
Intended Use	RMS High-FLO Super26™ Subcutaneous Needle Sets are indicated for subcutaneous infusion of medications in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling for the capacity for infusion of high flow rates including human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling for: Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring); and Cuvitru™ Immune Globulin Infusion (Human) 20% (manufactured by Shire).	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.
System components	Same as Predicate	Syringe Infusion System plus Needle Set
Needle Insertion Method	Same as Predicate	Manual
Angle of Insertion	Same as Predicate	90 degrees
Needle Material	Same as Predicate	Stainless Steel
Needle Gauge	Same as Predicate	26
Needle Length (mm)	Same as Predicate	4, 6, 9, 12, 14
Needle Usage	Same as Predicate	Single Use
Needle Set Configurations	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.	Available as a single-needle set, as well as 2-needle, 3-needle, 4- needle sets; through use of a Y-connector, 7-needle and 8-needle sets may also be assembled.
Needle Safety Feature	Same as Predicate	Yes
Tubing Length (inches)	Same as Predicate	20
Tubing Diameter (inches)	0.033	0.019
Tubing Material	Same as Predicate	Medical Grade PVC Plastic
Tubing Connection Type	Same as Predicate	Luer Tip
Provided Sterile	Same as Predicate	Yes
Sterilization Method	Same as Predicate	Gamma SAL 10^{-6}
Shelf Life	Same as Predicate	3 years
Packaging	Same as Predicate	Sterile Tubing and Needle Set
Indications for Use	Same as Predicate	Delivery of medication to the subcutaneous tissue

Discussion of differences:

Tubing Diameter: 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.

Needle Set Configurations: The subject device contains 5 and 6 needle sets used without the Y connector. These configurations are not available in the predicate.

These differences do not raise different questions of safety and effectiveness as compared to the predicate. Also, performance testing has been conducted to ensure these differences do not impact device safety and effectiveness and demonstrate the device performs as intended.

Biocompatibility Studies:

Biocompatibility testing had been conducted on the predicate device in accordance with ISO 10993 series standards. This testing included Modified ASTM Hemolysis (Direct Contact Method) testing was conducted, concluding that the difference between the hemolytic indexes of the test article, RMS Subcutaneous Needle Sets: 8-Needle Set Configuration [(2) 4-Needle Set Configuration connected via (1) RMS Y-Connector] and the negative control was 0.68 percent. This places the test article in a non-hemolytic range. The subject device and predicate device are manufactured utilizing identical materials and composition. Based on the identical materials and manufacturing processes between the predicate and subject device, RMS concludes that the performance test data on the predicate device demonstrates that HIgH-Flo Super26™ Subcutaneous Needle Set meets the biocompatibility requirements of ISO 10993.

Bench Performance Studies Included The Following Test Methods:

The subject device has the same technological characteristics as the predicate device which was cleared under K162613. The verification testing was limited to the following tests.

Flow Rate Testing:

Achievable Flow Rates with Super26™ and Specific Medications/Indications

NOTE: The tables below indicate the estimated maximum achievable flow rates with RMS HIgH-Flo Super26™ Subcutaneous Needle Sets when used in combination with RMS Precision Flow Rate Tubing™ and RMS Freedom Syringe Drivers.

Hizentra® PI with Super26™ - Max Flow Rate Per Site (ml/hr/site)

	F45	F60	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	4.5	5.8	10.6	13.4	19.5						
2 needles	2.3	3.0	5.6	7.2	10.9	17.0	17.3	20.9			
3 needles	1.5	2.0	3.8	4.9	7.6	12.1	12.3	15.1	20.8		
4 needles	1.2	1.5	2.9	3.7	5.8	9.4	9.5	11.8	16.5	22.5	
5 needles	0.9	1.2	2.3	3.0	4.7	7.6	7.8	9.6	13.7	18.9	
6 needles	0.8	1.0	1.9	2.5	3.9	6.5	6.6	8.2	11.7	16.3	
7 needles	0.7	0.9	1.7	2.2	3.4	5.6	5.7	7.1	10.2	14.3	
8 needles	0.6	0.8	1.5	1.9	3.0	4.9	5.0	6.3	9.1	12.8	23.5

Exceeds drug manufacturer's maximum indicated flow rate.

Subsequent infusions after 1st infusion only.

Hizentra® CIDP with Super26™ - Max Flow Rate Per Site (ml/hr/site)

	F45	F60	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	4.5	5.8	10.6	13.4	19.5	28.9	29.3	34.3	43.4		
2 needles	2.3	3.0	5.6	7.2	10.9	17.0	17.3	20.9	28.2	36.4	
3 needles	1.5	2.0	3.8	4.9	7.6	12.1	12.3	15.1	20.8	27.8	44.3
4 needles	1.2	1.5	2.9	3.7	5.8	9.4	9.5	11.8	16.5	22.5	37.6
5 needles	0.9	1.2	2.3	3.0	4.7	7.6	7.8	9.6	13.7	18.9	32.7
6 needles	0.8	1.0	1.9	2.5	3.9	6.5	6.6	8.2	11.7	16.3	28.9
7 needles	0.7	0.9	1.7	2.2	3.4	5.6	5.7	7.1	10.2	14.3	25.9
8 needles	0.6	0.8	1.5	1.9	3.0	4.9	5.0	6.3	9.1	12.8	23.5

Exceeds drug manufacturer's maximum indicated flow rate.
Subsequent infusions after 1st infusion only.

Cuvitru™ PI with Super26™ - Max Flow Rate Per Site (ml/hr/site)

	F45	F60	F120	F180	F275	F420	F500	F600	F900	F1200	F2400
1 needle	4.4*	5.7*	10.3	13.1	19.1	28.3	28.7	33.6	42.5	51.5	
2 needles	2.2*	2.9*	5.5*	7.1*	10.7	16.7	17.0	20.5	27.6	35.6	52.8
3 needles	1.5*	2.0*	3.7*	4.8*	7.4*	11.8	12.0	14.8	20.4	27.2	43.4
4 needles	1.1*	1.5*	2.8*	3.7*	5.7*	9.2*	9.3*	11.5	16.2	22.0	36.9

Exceeds drug manufacturer's maximum indicated flow rate.
Subsequent infusions after 1st two infusions only.

*Flow rate per site is lower then what is recommended on the biologic labe
NOTE: Drug manufacturer indicates maximum of up to four infusion sites

Conclusion:

The device performs as intended and is substantially equivalent to the predicate device.