January 28, 2026

KORU Medical Systems, Inc.
Emily Dimambro
Principal Regulatory Affairs Specialist
100 Corporate Dr.
Mahwah, New Jersey 07430

Re: K252015
Trade/Device Name: FreedomEdge Infusion System; High-Flo SubQ Needle Set; Precision Flow Rate Tubing
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, FPA, PKP
Dated: December 29, 2025
Received: December 29, 2025

Dear Emily Dimambro:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
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General Hospital, and Urology Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252015

Device Name
- FreedomEdge® Infusion Pump
- Precision Flow Rate Tubing™
- High-Flo SubQ Needle Sets™

Indications for Use *(Describe)*

The FreedomEdge® Syringe Infusion System consists of the following components:
- FreedomEdge® Infusion Pump
- Precision Flow Rate Tubing™
- High-Flo SubQ Needle Sets™

The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

For Immunoglobulin Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins in the home, hospital, or ambulatory settings when administered according to the FDA approved biologic labeling:
- Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®);
- Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®)
- Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid 20ml Single-use pre-filled syringe (manufactured by CSL Behring®)

For EMPAVELI™ (pegcetacoplan) Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.

For RYSTIGGO® (rozanolixizumab-noli) Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of RYSTIGGO® (rozanolixizumab-noli) when administered according to the approved drug product labeling.

For Intravenous Antibiotic Administration:
The FreedomEdge Infusion Pump and Precision Flow Rate Tubing are 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

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.

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K252015 510(K) SUMMARY

I. SUBMITTER

KORU Medical Systems, Inc.
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Phone Number: +1-800-624-9600

Contact Person:
Ms. Emily DiMambro
Principal Regulatory Affairs Specialist

Date Prepared: January 21, 2026

II. DEVICE

Name of Device: FreedomEdge® Infusion Pump
Precision Flow Rate Tubing™
High-Flo SubQ Needle Sets™
Common or Usual Name: Infusion Pump
Classification Name: Pump, Infusion (21CFR 880.5725)
Regulatory Class: II
Product Code: FRN, FPA, PKP

III. PREDICATE DEVICE

Name of Device: FreedomEdge® Syringe Infusion System (K214045)
Common or Usual Name: Infusion Pump
Classification Name: Pump, Infusion (21CFR 880.5725)
Regulatory Class: II
Product Code: FRN, FPA, PKP

IV. DEVICE DESCRIPTION

The FreedomEdge Infusion System is a non-electrically powered, mechanical infusion system which is intended for subcutaneous or intravenous administration of drug products in a home, ambulatory, or clinical setting. The infusion system includes the FreedomEdge Infusion Pump, the High-Flo SubQ Needle Sets, and the Precision Flow Rate Tubing Sets. The infusion system is designed to be used with sterile, single use syringes (not manufactured or sold by Koru Medical Systems) as the drug reservoir. There have been no significant changes to the technological features (e.g., material, design, energy source, packaging, sterility, manufacturing method) since the previous clearance.

The fundamental operating principle of the FreedomEdge Infusion System is based on the Hagen-Poiseuille equation. The syringe containing the drug to be infused is connected to the flow rate control tubing and the subcutaneous needle set or venous access device and inserted into the pump. The syringe pusher of the pump applies a constant force to the plunger of the syringe. The infusion sets generate a defined amount of resistance which determines the flow rate. Flow rates are modeled using the Hagen-Poiseuille equation and verified at the boundary conditions for the system.

The design and operating principles of the system and its components have not been significantly modified since the device was first cleared. The same test methods were used as in prior submissions. Acceptance criteria were generated for Rystiggo using the same flow rate prediction model as used in prior submissions.

V. INDICATIONS FOR USE

The FreedomEdge® Syringe Infusion System consists of the following components:

- FreedomEdge® Infusion Pump
- Precision Flow Rate Tubing™
- High-Flo SubQ Needle Sets™

The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).

For Immunoglobulin Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins in the home, hospital, or ambulatory settings when administered according to the FDA approved biologic labeling:

- Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®);
- Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®)
- Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid 20ml Single-use pre-filled syringe (manufactured by CSL Behring®)

For EMPAVELI™ (pegcetacoplan) Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.

For RYSTIGGO® (rozanolixizumab-noli) Administration:
The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of RYSTIGGO® (rozanolixizumab-noli) when administered according to the approved drug product labeling.

For Intravenous Antibiotic Administration:
The FreedomEdge Infusion Pump and Precision Flow Rate Tubing are 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Indications for Use Comparison
The table following includes a comparison of the indications for use between the new device and that of the predicate device:

Table 1: Comparison of Indications for Use

Cleared Indications for Use (K214045):	Modified Indications for Use	Description of Change:
The FreedomEdge® Syringe Infusion System consists of the following components: • FreedomEdge® Syringe Driver • Precision Flow Rate Tubing™ • HIgH-Flo Subcutaneous Safety Needle Sets™ • HIgH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration. The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).	The FreedomEdge® Syringe Infusion System consists of the following components: • FreedomEdge® Infusion Pump • Precision Flow Rate Tubing™ • High-Flo SubQ Needle Sets™ The FreedomEdge® Syringe Infusion System is indicated for use with the BD® 20 ml syringe (US Reference number: 302830), BD 30 ml syringe (US Reference number: 302832) and Hizentra® 20 ml prefilled syringe (NDC 44206-458-96).	- Removed Super26 Subcutaneous Needle Sets. These devices are no longer manufactured or sold. - Modified FreedomEdge and High Flo names to align with current branding. These changes are clerical in nature and do not represent a change to the use of the device.
For Immunoglobulin Administration: 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: Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) and Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) Single-use pre-filled syringe for subcutaneous administration in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling. **For EMPAVELI™ (pegcetacoplan) Administration:** The Freedom Integrated Syringe Infusion System is specifically indicated for the subcutaneous infusion of EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.	**For Immunoglobulin Administration:** The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins in the home, hospital, or ambulatory settings when administered according to the FDA approved biologic labeling: • Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); • Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); • Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®) • Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid 20ml Single-use pre-filled syringe (manufactured by CSL Behring®) **For EMPAVELI™ (pegcetacoplan) Administration:** The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of EMPAVELI™ (pegcetacoplan) in the home, hospital, or ambulatory setting when administered according to the approved drug product labeling.	Formatting change only. The change does not affect the use of the device.
n/a	**For RYSTIGGO (rozanolixizumab-noli) Administration:** The FreedomEdge Infusion System is specifically indicated for the subcutaneous infusion of RYSTIGGO (rozanolixizumab-noli) when administered according to the approved drug product labeling.	Rystiggo will be added to the Indications for Use. **This change is the subject of this submission.**
For Intravenous Antibiotic Administration: The Freedom Integrated Syringe Infusion System with the FreedomEdge® Syringe Driver and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: Ertapenem, Meropenem, Oxacillin, and Tobramycin.	**For Intravenous Antibiotic Administration:** The FreedomEdge Infusion Pump and Precision Flow Rate Tubing are 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.	Modified device names to align with current branding. These changes are clerical in nature and do not represent a change in the use of the device.

Technological Characteristics Comparison:

The following table summarizes the technological characteristrics of the subject device in comparison to the predicate device.

Table 2: Comparison of Technological Characteristics

Characteristic:	Predicate (K214045):	Subject Device:	Description of Change:
Intended Use:	Subcutaneous or intravenous infusion of prescribed drugs and biologics	No change	No change to intended purpose. Rystiggo is indicated for subcutaneous administration using an infusion pump.
System Components:	FreedomEdge Infusion Pump High-Flo Subcutaneous Needle Sets Super26 Subcutaneous Needle Sets Precision Flow Rate Tubing	FreedomEdge Infusion Pump High-Flo SubQ Needle Sets Precision Flow Rate Tubing	The change to remove the Super26 Subcutaneous Needle Sets as a compatible needle set does not affect the safety and effectiveness of the FreedomEdge Infusion System. Super26 is being removed from the Indications for Use because it is no longer manufactured or sold,
Materials of Construction:	**FreedomEdge:** ABS, Acetal, Stainless Steel (18-8, 301, 12L14, 303), Aluminum, Polycarbonate, Polyurethane, Nitrile (synthetic) rubber **High-Flo Subcutaneous Needle Sets:** Non-DEHP PVC tubing, Molded PVC (non-DEHP), Polypropylene, Stainless Steel, MABS, SBS, Tegaderm, Acrylated Urethane (UV Glue) **Precision Flow Tubing Sets and FEXT:** Non-DEHP PVC tubing, Molded PVC (non-DEHP), Polypropylene, Acrylated Urethane (UV Glue) **Y Connector:** Molded PVC (non-DEHP)	No change	There are no changes to the device materials.
Sterile Device Packaging Material:	Nylon	No change	There are no changes to the sterile device packaging material.
Sterilization Method:	Gamma radiation – 25-40kGy (Validated using VDMax method)	No change	There are no changes to the sterilization method, sterilization parameters, or validation method.
Principle of Operation:	The pump exerts constant force on the syringe plunger. The resistance of the flow tubing and needle set determines the flow rate. Flow rates for infusion set combinations are modeled using the Hagen-Poiseuille equation, taking into consideration the drug viscosity, fluid path dimensions, and pressure generated by the pump. Flow rate tables are given in the IFU to allow prescribers to select the appropriate combinations of flow tubing and needle sets to meet the drug infusion parameters.	No change.	There is no change to the fundamental operating principle of the FreedomEdge Infusion System. The same verification methods can be used to verify the flow rates delivered by the FreedomEdge Infusion System. The same verification methods as submitted in prior 510ks were used to verify the flow rates delivered by the FreedomEdge Infusion System. To meet the infusion parameters given in the Rystiggo prescribing information, specific combinations of infusion sets and the resulting flow rates are specified in the FreedomEdge Instructions for Use.
Indicated substances:	**Subcutaneous administration:** Hizentra Hizentra 20ml Prefilled Syringe Cuvitru Gammagard Empaveli (pegcetacoplan)	**Subcutaneous administration:** Hizentra Hizentra 20ml Prefilled Syringe Cuvitru Gammagard Empaveli	**Change is subject of this submission**. Rystiggo is a high viscosity biologic drug product with similar properties to the drugs and biologics that are currently cleared for use with the system. Compatibility of Rystiggo with the FreedomEdge Infusion System has been verified through

Characteristic:	Predicate (K214045):	Subject Device:	Description of Change:
	Intravenous administration: Ertapenem, Meropenem, Oxacillin, and Tobramycin	(pegcetacoplan) Rystiggo **Intravenous administration:** Ertapenem, Meropenem, Oxacillin, and Tobramycin	performance testing in accordance with the same established test methods as previously used for the FreedomEdge Infusion System. The risk evaluation for the device and the verification evidence demonstrates that the device risk profile is equivalent to the predicate device. Addition of this drug does not introduce new questions of safety and effectiveness and therefore comparison can be made to the predicate FreedomEdge device.
Prescription/Over the Counter:	Prescription	No change	No change.
Use Environment and Intended Users:	Home, ambulatory, or clinical use Healthcare provider or lay user (caregiver or patient) use	No change	Rystiggo is approved for administration by a healthcare provider only. The FreedomEdge was previously cleared for this user group and thus the addition of Rystiggo does not add new or different user groups or use environments and therefore does not introduce new or different risks as compared to the predicate.
Intended Patient Population:	Adult, pediatric	No change	No change. Rystiggo is indicated for use in adults.
Syringe Compatibility:	BD 20ml Syringe BD 30 ml Syringe Hizentra 20ml Prefilled Syringe	No change	No change. The flow rates for Rystiggo administration have been verified with a 20ml BD syringe.
Flow Rate Accuracy:	±15%	No change	No change. Flow rates are verified using the same test method and accuracy acceptance criteria.
Device Dimensions	9.5” × 3.25” × 1.5”	9.5” × 3.25” × 1.5”	No change. The addition of Rystiggo does not change the device dimensions.
Device Weight	0.7 lb	0.7 lb	No change. The addition of Rystiggo does not change the device weight.
Shelf-Life (for Sterile Components)	**High-Flo Subcutaneous Needle Sets:** 3 years **Precision Flow Tubing Sets and FEXT:** 5 years **Y Connector:** 5 years	No change	No change. The addition of Rystiggo does not change the shelf-life.
Storage Conditions	Room temperature	No change	No change. The addition of Rystiggo does not change the storage conditions.
Performance Testing Summary	Flow Rate Verification Potency Evaluation	Flow Rate Verification Potency Evaluation	No change. The performance testing methods and acceptance criteria are the same as the predicate device.

Substantial Equivalence Discussion:

The only change made to the FreedomEdge Infusion System in comparison to the predicate device is the addition of Rystiggo to the Indications for Use as a compatible drug. The FreedomEdge Infusion System was previously cleared for the subcutaneous infusion route. Therefore, addition of another biologic for subcutaneous administration does not expand or modify the intended purpose of the infusion system.

The fundamental operating principles and device design are not impacted by the change. There are no changes to the physical features (including materials, design, energy source, dimensions, or packaging) from those of the predicate FreedomEdge Infusion Pump. There are no changes to the dimensions, materials, packaging, labeling, sterility, or any other features for the High-Flo SubQ Needle Sets and Precision Flow Rate Tubing Sets. There are no other significant technological or manufacturing changes being made to the device design/manufacture, fundamental operating principles, or device labeling that would potentially impact safety and effectiveness.

The modification to add Rystiggo to the indications for use does not introduce new or different questions of safety and effectiveness. Rystiggo is indicated for administration by a healthcare provider only. The FreedomEdge was previously cleared for use in a home or clinical environment by lay users (caregivers or patients) and healthcare providers; therefore, adding Rystiggo to the indications does not introduce new or modified use-related risks in comparison to the predicate device. Compatibility of Rystiggo with the FreedomEdge Infusion System has been verified through performance testing using similar test methods as previously used for the FreedomEdge Infusion System. The verification testing demonstrated that the device is able to deliver Rystiggo in accordance with the infusion parameters specified in the drug labeling, and that the drug is not negatively impacted by being administered with the infusion system. Biocompatibility evaluation concluded that use of Rystiggo with the infusion system does not affect the biological safety of the device in comparison to the predicate device.

The risk assessment documentation completed to support the change demonstrates that the addition of Rystiggo does not introduce any new or modified risks in comparison to the predicate FreedomEdge. All risks related to administration of Rystiggo have been addressed with risk control measures and have been adequately reduced to a safe level.

In accordance with the requirements described in “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, the comparison tables above and the objective evidence presented in this submission are sufficient to support that the subject FreedomEdge Infusion System has the same intended use as the predicate, the technological characteristics do not raise new questions of safety and effectiveness and the information contained in this submission is sufficient to show that the FreedomEdge is equivalently safe and effective in comparison to the predicate FreedomEdge device.

VII. PERFORMANCE DATA

The following performance testing/verification testing was completed to support the safety and effectiveness of the subject device:

- Flow rate/flow accuracy
- Chemical compatibility (i.e., extractables and leachables)
- Potency/drug compatibility with the fluid path

Clinical testing was not submitted or performed to support substantial equivalence.

The conclusions drawn from the non-clinical testing demonstrate the following:

- The FreedomEdge Infusion System is capable of infusing Rystiggo at the flow rates specified in the FDA-approved drug product labeling
- The Hagen-Poiseuille flow rate model (as previously discussed in K214045 and K211206) can be used to model the flow rates for Rystiggo when administered by the FreedomEdge Infusion System). The flow rates delivered by the system are within the same accuracy and

confidence level as previously established for the FreedomEdge Infusion System in predicate submissions.

- The potency testing demonstrated that Rystiggo will maintain its potency after being infused with the FreedomEdge Infusion System
- Polarity evaluation demonstrated that Rystiggo falls within the polarity range for the solvents previously used in extractables and leachables testing for the sterile infusion devices. The previously conducted chemical characterization testing is therefore valid to demonstrate the chemical compatibility of Rystiggo with the FreedomEdge Infusion System.

VIII. CONCLUSIONS

The subject device 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 subject device 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 and predicate device do not raise different questions of safety or effectiveness. Based on performance testing results, the subject device, performs as intended and performs comparably to the predicate device that is currently marketed for the same intended use.