December 30, 2020

DEKA Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial Street
Manchester, New Hampshire 03101

Re: K202690
Trade/Device Name: Remunity Subcutaneous Delivery System for Remodulin
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: QJY
Dated: December 4, 2020
Received: December 4, 2020

Dear Paul Smolenski:

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 and Part 809); 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,

For CAPT. Alan Stevens
Acting Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202690

Device Name
Remunity Subcutaneous Delivery System for Remodulin®

Indications for Use *(Describe)*
The Remunity Subcutaneous Infusion System (the Remunity System) is intended for continuous subcutaneous delivery of Remodulin® (treprostinil) Injection for use in adults (greater than 22 years of age).

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 – K202690

Submitter Information

510(k) Sponsor:	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person	Paul Smolenski Regulatory Affairs DEKA Research & Development Corporation Phone: (603) 669-5139 Fax: (603) 624-0573 psmolenski@dekaresearch.com
Date Prepared:	December 18, 2020

Proposed Device

Common/Usual Name:	Infusion Pump
Trade/Proprietary Name:	Remunity Subcutaneous Delivery System for Remodulin®
Classification Name:	Infusion Pump
Device Classification:	880.5725
Product Code:	QJY, Infusion pump, drug specific, pharmacy-filled
Class	II
Device Panel:	General Hospital

Predicate Device

Unity Subcutaneous Delivery System for Remodulin K191313.

No reference devices are used in this submission.

Device Description

The Remunity Subcutaneous Delivery System for Remodulin® (Remunity System) is a wearable infusion pump designed to deliver Remodulin® for the treatment of pulmonary arterial hypertension (PAH). It is intended for continuous subcutaneous delivery of FDA-approved Remodulin® (treprostinil) (hereinafter referred to as 'Remodulin®' or 'Remodulin® (treprostinil)'), NDA 021272. The Remunity System consists of several components: a wearable pump assembly, a remote interface, a filling and priming aid, and accessories (e.g., rechargeable batteries, battery charger, charging cable, power adapter). A commercially available subcutaneous infusion set is connected to the pump assembly via a standard luer connector for the delivery of Remodulin® from the Remunity System to the patient.

The pump assembly is composed of a reusable pump and a disposable single-use cassette with a pharmacy-filled drug reservoir, which infuses Remodulin® subcutaneously into the patient based on an individualized programmed rate. Each disposable cassette may be used for up to 72 hours after attachment to the pump. The Remunity System utilizes a micro-dosing pump mechanism supplemented with acoustic volume sensor feedback to ensure delivery accuracy.

The pharmacy-filled cassette is intended to be stored (inclusive of shipping time) up to 14-days and is intended to be in use for up to 72-hours. The cassettes are identical to those cleared under K191313, with the exception that the luer lock cap material was changed from Polycarbonate to ABS.

The device is prescription use only.

Indications for Use

The Remunity Subcutaneous Infusion System (the Remunity System) is intended for continuous subcutaneous delivery of Remodulin® (treprostinil) Injection for use in adults (greater than 22 years of age).

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a summation matrix of the intended use between the new device and those of the current device:

Characteristic	Unity Subcutaneous Deliver System for Remodulin® K191313	**Proposed** Remunity Subcutaneous Deliver System for Remodulin®
Indications for Use	The Unity Subcutaneous Delivery System for Remodulin® (the Unity System) is intended for continuous subcutaneous delivery of Remodulin® (treprostinil) injection for use in adults (greater than 22 years of age).	Same Indications for Use. Branding has been updated from "Unity" to "Remunity".
Prescription Only or Over the Counter	Prescription Only	No Change
Intended Population	Adults (>22 years of age)	No Change
Environment of Use	In professional healthcare facility and home healthcare environments	No Change

Discussions of differences in Indications for Use statement

The indications for use for the subject device is the same as the device cleared under K191313. The branding of the device has been updated from “Unity” to “Remunity”.

Discussions of differences in intended population

The intended population for the subject device is identical to the predicate device cleared under K191313.

The Remunity system is indicated for adults (greater than 22 years of age)

Discussions of differences in environment of use

The environment of use for the subject device is identical to the predicate device cleared under K191313.

Comparison of Technological Characteristics with the Predicate Device

The below table compares the characteristics of the subject device to the Unity System cleared under K191313 and includes an assessment of differences between them and why the differences between the subject device and predicate device do not introduce new or different questions of safety and effectiveness.

Characteristic	**Predicate Device** Unity Subcutaneous Deliver System for Remodulin® K191313	**Subject Device** Remunity Subcutaneous Deliver System for Remodulin®	Discussion of Differences
Mechanism of action	Microprocessor controlled Micro- dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy.	Same	N/A
Infusion Accuracy	±6%	Same	N/A
Maximum Infusion pressure	<16.4 psi (<113 kPa)	Same	N/A
Programmable Flow rate ranges	16 µl/hr to 225 µl/hr with increments of 1 µl/hr	Same	N/A
Time to occlusion alarm	Maximum time to occlusion alarm: <12 min. at rates ≥ 100 µl/hr within 8 hr, at rates < 100 µl/hr	Same	N/A

Characteristic	**Predicate Device** Unity Subcutaneous Deliver System for Remodulin® K191313	**Subject Device** Remunity Subcutaneous Deliver System for Remodulin®	Discussion of Differences
Post-occlusion bolus	<40 µl at all rates.	Same	N/A
Alarms & Alerts	• Battery depleted • Battery Low (pump) • Battery Low (remote) • Cassette Depleted • Cassette Problem • Cassette Removed • Depletes Soon • Pump Error • Pump Failure • Occlusion • Delivery Stopped • Basal Not Started • Idle • Software Version Error • Tech • Excessive Noise • No Communication • Message Timeout • Pairing Failed • Walkaway	Same	N/A
Device Service Life	3 years	Same	N/A

Characteristic	**Predicate Device** Unity Subcutaneous Deliver System for Remodulin® K191313	**Subject Device** Remunity Subcutaneous Deliver System for Remodulin®	Discussion of Differences
Dimensions & Weight	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in) 50 g (1.76 oz)	Same	N/A
Materials	*Cassette fluid path*: Polycarbonate, Bromobutyl, SEBS, polyurethane *Pump*: ABS, Polycarbonate, Aluminum *Cartridge*: Polycarbonate, Acrylic, polyurethane *Filling Aid*: PC-ABS *Luer Lock Cap*: Polycarbonate	*Cassette fluid path*: Polycarbonate, Bromobutyl, SEBS, polyurethane *Pump*: ABS, Polycarbonate, Aluminum *Cartridge*: Polycarbonate, Acrylic, polyurethane *Filling Aid*: PC-ABS *Luer Lock Cap*: ABS	The change in luer lock cap material was evaluated to the same standards for biocompatibility under ISO-10993-1 as the predicate. The revised material demonstrates equivalent biocompatibility. Functional (container closure) testing was performed. Subject device was found to be equivalent to the predicate.
Environment of Use	In professional healthcare facility and home healthcare environments	Same	N/A
Ingress protection	IP58 when connected to the reservoir	Same	N/A
Power source	Rechargeable Lithium-Ion Battery	Same	N/A
Storage Conditions	Temperature: -13˚F to 158˚F (-25˚C to 70˚C) Non-condensing humidity: up to 90%. Pressure: 500 hPa to 1060 hPa	Same	N/A

Characteristic	**Predicate Device** Unity Subcutaneous Deliver System for Remodulin® K191313	**Subject Device** Remunity Subcutaneous Deliver System for Remodulin®	Discussion of Differences
Operating Conditions	Temperature: 41˚F to 104˚F (5˚C to 40˚C) Non-condensing humidity: up to 90% Pressure: 700 hPa to 1060 hPa	Same	N/A
Remote user feedback	Audible, vibratory	Same	N/A
Administration Set	Medtronic Quick-set Infusion Set Medtronic Silhouette and Infusion Set Smiths Medical Cleo 90 Infusion Set	Same	N/A
Cassette	Remodulin Unity cassettes, 3 ml, Specialty Pharmacy filled	Same	N/A
Expiration – Cassette	Pharmacy-Fill, 14 Days (*consistent with USP 797*)	Same	N/A
End User Packaging -	Aseptically filled cassette with female luer lock fluid path closure, placed in plastic clamshell tray and sealed in foil pouch	Same	N/A
Biocompatibility	Complies with ISO 10993-1 and the Agency's "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a Risk Management Process' – Guidance for Industry and Food and Drug Administration Staff" dated June 16, 2016	Same	N/A
Luer Lock Cap packaging	Tyvek/LDPE pouch	Same	N/A

Characteristic	Predicate Device Unity Subcutaneous Deliver System for Remodulin® K191313	Subject Device Remunity Subcutaneous Deliver System for Remodulin®	Discussion of Differences
Luer Lock Cap sterility assurance level	SAL 10^{-6}	Same	N/A

Non-Clinical/ Performance Testing:

The safety assurance case provided for the Remunity Subcutaneous Delivery System for Remodulin® as recommended in the FDA guidance document, "Infusion Pumps Total Product Life Cycle" and cleared under premarket notification K191313 applies to the subject device in all aspects.

The stated goal of the safety assurance case ("safety case") is: "The Remunity Subcutaneous Infusion System for Remodulin® is adequately safe for its intended use."

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The assurance case was updated to reflect the new luer lock cap material and continues to cover all system attributes that were stated for the predicate:

- All hazards associated with the system have been identified and adequately addressed
- Device reliability is adequate
- The device design requirements are adequately verified and validated

The arguments specific to the luer lock cap material change were updated from that of the predicate K191313. Since the assurance case builds on the original case, only evidence used to provide assurance related to the changes are listed here:

Container Closure performance	Performance of the device to maintain adequate assurance of protection from microbial ingress was evaluated through container closure testing.
Biocompatibility	The materials used for the Remunity System comply with biocompatibility requirements outlined in ISO 10993-1:2009 and the "Guidance for Industry and Food and Drug Administration Staff, 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.

Clinical Study

No clinical data was obtained in support of this premarket submission.

Design Control

The Remunity System was specified and developed by DEKA. DEKA is a registered medical device specification developer and complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as registered to ISO 13485.

Conclusion

The modifications in the luer lock cap material do not change the intended use or technological characteristics of the subject device compared to the Unity System cleared under premarket notification K191313. The changes summarized in this submission do not raise different questions of safety and effectiveness.

The performance of the device is supported by DEKA's design control process which included non-clinical testing and risk management activities. The Remunity Subcutaneous Delivery System for Remodulin® is Substantially Equivalent (SE) to the Remunity Subcutaneous Delivery System for Remodulin® cleared under premarket notification K191313.