November 27, 2024

DEKA Research & Development Corp.
Paul Smolenski
Director of Regulatory Affairs
340 Commercial Street
Manchester, New Hampshire 03101

Re: K243354
Trade/Device Name: Remunity System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: QJY
Dated: October 28, 2024
Received: October 29, 2024

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 (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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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243354

Device Name
Remunity system

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

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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DEKA Research & Development Corp.

K243354 510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

Submitter Information

510(k) Sponsor	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person(s)	Paul Smolenski (primary), Lauren Blake (secondary) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 psmolenski@dekaresearch.com, lblake@dekaresearch.com
Date Prepared	October 28, 2024

Proposed Device(s)

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

Predicate Device(s)

The predicate device is the Remunity Subcutaneous Delivery System for Remodulin®, which was previously cleared under premarket application K191313 on February 12, 2020.

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 or user-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 device is prescription use only.

The modified device can be used with an additional infusion set.

Indications for Use

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

Substantial Equivalence Discussion

The following table is a matrix of the intended use and technological characteristics between the subject device and the predicate device. The table also discusses why these differences do not introduce new or different questions of safety and effectiveness.

Characteristic	**Predicate Device – Remunity System (K191313)**	**Subject Device – Modified Remunity System**	**Equivalence**
Device Classification Regulation and Product Code	21 CFR 880.5725 Product Code: QJY	21 CFR 880.5725 Product Code: QJY	**No change**
Class	II	II	**No change**
Indications for Use	The Remunity® Pump for Remodulin® (treprostinil) Injection (the Remunity System) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years old).	The Remunity® Pump for Remodulin® (treprostinil) Injection (the Remunity System) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years old).	**No change**
Prescription Use or Over the Counter (OTC)	Prescription	Prescription	**No change**

Characteristic	Predicate Device – Remunity System (K191313)	Subject Device – Modified Remunity System	Equivalence
Intended Patient Population	Age >22 years	Age >22 years	**No change**
Patient Environment	On-body wearable ambulatory pump	On-body wearable ambulatory pump	**No change**
Environment of Use	In professional healthcare facilities and home environments	In professional healthcare facilities and home environments	**No change**
Delivery Method	Microprocessor controlled micro-dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy	Microprocessor controlled micro- dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy	**No change**
Delivery type	Subcutaneous infusion	Subcutaneous infusion	**No change**
Dimensions	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in)	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in)	**No change**
Weight	50 g (1.76 oz.)	50 g (1.76 oz.)	**No change**
Basal Delivery Rate Range	16 µL/hr – 225 µL/hr, with increments of 1 µL/hr	16 µL/hr – 225 µL/hr, with increments of 1 µL/hr	**No change**
Basal Accuracy	±6%	±6%	**No change**
Bolus Volume after Occlusion Release	< 40 µL at all rates	< 40 µL at all rates	**No change**
Time to Occlusion Alarm	Maximum time to occlusion alarm: • *≥ 100 µL/hr:* 12 minutes • *< 100 µL/hr:* 8 hours	Maximum time to occlusion alarm: • *≥ 100 µL/hr:* 12 minutes • *< 100 µL/hr:* 8 hours	**No change**
Pump Service Life	3 years	3 years	**No change**
Ingress Protection	IP58 when connected to the Cassette	IP58 when connected to the Cassette	**No change**
Applicable Safety Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-24 • ISO 11137-1 (Sterilized via Gamma Radiation) • ISO 10993-1 • ISO 14971	**No change**
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	**No change**

Characteristic	Predicate Device – Remunity System (K191313)	Subject Device – Modified Remunity System	Equivalence
Pump Storage Conditions	Temperature: -25 °C to 70 °C (-13 °F to 158 °F) Non-condensing Humidity: up to 90% Pressure: 50 kPa to 106 kPa	Temperature: -25 °C to 70 °C (-13 °F to 158 °F) Non-condensing Humidity: up to 90% Pressure: 50 kPa to 106 kPa	**No change**
Operating Conditions	Temperature: 5 °C to 40 °C (41 °F to 104 °F) Non-condensing Humidity: up to 90% Pressure: 70 kPa to 106 kPa	Temperature: 5 °C to 40 °C (41 °F to 104 °F) Non-condensing Humidity: up to 90% Pressure: 70 kPa to 106 kPa	**No change**
Remote Interface	Touchscreen Device	Touchscreen Device	**No change**
System User Feedback	Visual, audible, vibratory	Visual, audible, vibratory	**No change**
Common Alarms	Battery Depleted Cassette Depleted Cassette Removed Cassette Problem Occlusion Pump Error Pump Failure Basal Not Started Adjust Pump Delivery Stopped Depletes Soon Excessive Noise Message Timeout No Communication Pairing Failed Pairing Lost Pump Idle Pump Battery Low Remote Battery Low Request Refused Software Version Error Tech Walkaway	Battery Depleted Cassette Depleted Cassette Removed Cassette Problem Occlusion Pump Error Pump Failure Basal Not Started Adjust Pump Delivery Stopped Depletes Soon Excessive Noise Message Timeout No Communication Pairing Failed Pairing Lost Pump Idle Pump Battery Low Remote Battery Low Request Refused Software Version Error Tech Walkaway	**No change**
Battery Operating Time	72 hours	72 hours	**No change**

Characteristic	Predicate Device – Remunity System (K191313)	Subject Device – Modified Remunity System	Equivalence
Infusion Set	• Medtronic Quick-set Infusion Set [K991759] o 23" (MMT-392, MMT-393) • Medtronic Silhouette Infusion Set [K162812] o 23" (MMT-373) • Smiths Medical Cleo 90 Infusion Set [K042172] o 24" (21-7220-24, 21-7230-24)	• Medtronic Quick-set Infusion Set [K991759] o 23" (MMT-392, MMT-393) • Medtronic Silhouette Infusion Set [K162812] o 23" (MMT-373) • Smiths Medical Cleo 90 Infusion Set [K042172] o 24" (21-7220-24, 21-7230-24) • **Neria Guard Infusion Set [K192647]** o **23" (704060-5226, 704060-5229)**	**Equivalent** The subject device has an additional compatible infusion set. The Neria Guard infusion set has similar physical characteristics to other currently listed infusion sets. Performance testing with the Neria Guard demonstrates that subject device performance is equivalent to the predicate device. The methods and acceptance criteria used in this testing are well established in previous clearances.
Compatible Cassette	Remodulin Unity Cassettes, 3 mL	Remodulin Unity Cassettes, 3 mL	**No change**
Cassette Filling Method	• Specialty pharmacy • User-filled	• Specialty pharmacy • User-filled	**No change**
Cassette Shelf Life (empty)	2 years	2 years	**No change**
Pharmacy-filled Shelf-Life	14 days (per <USP 797>)	14 days (per <USP 797>)	**No change**
Material Biocompatibility	Cassette fluid path: Polycarbonate (PC), Bromobutyl, SEBS, polyurethane Pump: ABS, PC, Aluminum Cartridge: PC, Acrylic, polyurethane Filling Aid: PC-ABS Cap (Pharmacy-fill): ABS	Cassette fluid path: Polycarbonate (PC), Bromobutyl, SEBS, polyurethane Pump: ABS, PC, Aluminum Cartridge: PC, Acrylic, polyurethane Filling Aid: PC-ABS Cap (Pharmacy-fill): ABS	**No change**

Characteristic	Predicate Device – Remunity System (K191313)	Subject Device – Modified Remunity System	Equivalence
Pharmacy-fill End-user Packaging	Aseptically filled cassette with female luer lock fluid path closure, placed in plastic clamshell tray and sealed in foil pouch	Aseptically filled cassette with female luer lock fluid path closure, placed in plastic clamshell tray and sealed in foil pouch	**No change**
Priming Method	Manually primed by user before Cassette attachment to the Pump	Manually primed by user before Cassette attachment to the Pump	**No change**

Animal, Clinical, and Bench Data

Bench performance testing was conducted in order to qualify the additional infusion set for use with the subject device, and to establish substantial equivalence to the predicate device in terms of safety and effectiveness.

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

Design Control

The Remunity System was specified and developed by DEKA. DEKA complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as to ISO 13485:2016.

Conclusion

The subject Remunity System is substantially equivalent to the predicate Remunity System, cleared under premarket application K191313, cleared on February 21, 2020. The differences 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.