June 12, 2024

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

Re: K240256
Trade/Device Name: Remunity System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: QJY
Dated: May 9, 2024
Received: May 10, 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.

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
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and Human Factors
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240256

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.

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	January 30, 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 K202690 on December 30, 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 utilizes a touchscreen remote controller.

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

Intended Use Comparison

The tables below includes a matrix of the intended use between the subject device and the predicate device.

Characteristic	**Predicate Device – Remunity System (K202690)**	**Subject Device – Remunity System**
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).	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).

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System
Prescription Use or Over the Counter (OTC)	Prescription	No change
Intended Patient Population	Greater than 22 years of age	No change
Patient Environment	On-body wearable ambulatory pump	No change
Environment of Use	In professional healthcare facilities and home environments	No change

The intended use remains unchanged in the subject device with respect to the predicate device (K202690). The Indications for Use have been updated to reflect the current branding for the device. This update does not affect the intended patient population or environment of use.

Technological Characteristic Comparison

The table below compares the characteristics of the predicate and subject devices, and includes an assessment of the differences and why these differences do not introduce new or different questions of safety and effectiveness.

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
Delivery Method	Microprocessor controlled micro-dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy	Same	N/A
Delivery type	Subcutaneous infusion	Same	N/A
Dimensions	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in)	Same	N/A
Weight	50 g (1.76 oz.)	Same	N/A
Basal Delivery Rate Range	16 µL/hr – 225 µL/hr, with increments of 1 µL/hr	Same	N/A
Basal Accuracy	±6%	Same	N/A

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
Bolus Volume after Occlusion Release	< 40 µL at all rates	Same	N/A
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	N/A
Pump Service Life	3 years	Same	N/A
Ingress Protection	IP58 when connected to the Cassette	Same	N/A
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	Same	N/A
Power Source	Rechargeable Lithium Ion Battery	Same	N/A
Pump Storage Conditions	Temperature: -25 °C to 70 °C (-13 °F to 158 °F) Humidity: up to 90% Pressure: 50 kPa to 106 kPa	Same	N/A
Operating Conditions	Temperature: 5 °C to 40 °C (41 °F to 104 °F) Humidity: up to 90% Pressure: 70 kPa to 106 kPa	Same	N/A

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
Remote Interface	• Push-button device	• Touchscreen device	Equivalent The subject device provides a touchscreen device for use with the pump. The text and format of information displayed to the user, as well as workflows and required user input remains unchanged. No additional risks have been introduced.
System User Feedback	Visual, audible, vibratory	Same	N/A

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
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	Same	N/A
Battery Operating Time	72 hours	Same	N/A

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
Infusion Set	Medtronic Quick-set Infusion Set [K991759] • 42" (MMT-390, MMT-391) • 23" (MMT-392, MMT-393) Medtronic Silhouette Infusion Set [K162812] • 23" (MMT-373) Smiths Medical Cleo 90 Infusion Set [K042172] • 24" (21-7220-24, 21-7230-24) • 31" (21-7221-24, 21-7231-24) • 42" (21-7222-24, 21-7232-24)	Same	N/A
Compatible Cassette	Remodulin Unity Cassettes, 3 mL	Same	N/A
Cassette Filling Method	• Specialty pharmacy • User-filled	Same	N/A
Cassette Shelf Life (empty)	2 years	Same	N/A
Pharmacy-filled Shelf-Life	14 days (per <USP 797>)	Same	N/A

Characteristic	Predicate Device – Remunity System (K202690)	Subject Device – Remunity System	Equivalence
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	Same	N/A
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	Same	N/A
Priming Method	Manually primed by user before Cassette attachment to the Pump	Same	N/A

Performance Data

Performance testing was conducted in order to verify and validate the subject device remote interface for its intended use, and to establish substantial equivalence to the respective predicate device remote interface in terms of safety and effectiveness. The FDA Guidance Document, *Infusion Pumps Total Product Life Cycle*, issued December 2, 2014 was followed.

Device Performance	The following functional areas, specific to the remote interface, were evaluated: • Touchscreen Remote Reliability • Touchscreen Remote Functionality • Wireless Communication
Software and Cybersecurity	The subject device is considered to require an "Enhanced Documentation Level" per the 2023 FDA guidance document.

	Software and Cybersecurity testing was conducted per ANSI AAMI IEC 62304:2006/A1:2016 and the following FDA Guidance Documents: • *Content of Premarket Submissions for Device Software Functions,* issued June 14, 2023 • *Off-The-Shelf Software Use in Medical Devices*, issued September 27, 2019 • *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued September 27, 2023 • *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issued April 8, 2020 • *Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act,* issued March 30, 2023
Human Factors	The human factors evaluation followed the FDA Guidance Document, *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, and the following standards: • IEC 60601-1-6:2020 • ANSI AAMI IEC 62366-1:2015+A1:2020
Electrical Safety	Per IEC 60601-1:2020
EMC	Per IEC 60601-1-2:2020
Alarms	Per IEC 60601-1-8:2020

Animal and Clinical Studies

No animal study or clinical trial 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 differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Remunity Subcutaneous Delivery System for Remodulin® is substantially equivalent to the Remunity Subcutaneous Delivery System for Remodulin® cleared under K202690 with respect to the indications for use, target populations, treatment method, and technological characteristics.