March 11, 2025

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

Re: K250357
Trade/Device Name: RemunityPRO™ Pump for Remodulin® (treprostinil) Injection
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: February 7, 2025
Received: February 7, 2025

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,

Rebecca Dorsey -S

For
Jake Lindstrom, Ph.D.
Assistant 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K250357

Device Name
RemunityPRO™ Pump for Remodulin® (treprostinil) Injection

Indications for Use *(Describe)*
The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection (the RemunityPRO System) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K250357 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 Corp.<br>340 Commercial Street<br>Manchester, NH 03101 |
| **Contact Person(s)** | Paul Smolenski (primary), Lauren Blake (secondary)<br>Regulatory Affairs<br>Phone: (603) 669-5139<br>Fax: (603) 624-0573<br>psmolenski@dekaresearch.com, lblake@dekaresearch.com |
| **Date Prepared** | March 4, 2025 |

## Proposed Device(s)

| | |
|---|---|
| **Common/Usual Name:** | Infusion Pump |
| **Trade/Proprietary Name:** | RemunityPRO™ Pump for Remodulin® (treprostinil) Injection |
| **Classification Name:** | Infusion Pump |
| **Device Classification:** | 880.5725 |
| **Product Code:** | FRN |
| **Class:** | II |
| **Device Panel:** | General Hospital |

## Predicate Device

The predicate device is the Remunity® 2.0 Pump for Remodulin® (treprostinil) Injection, K241736, cleared on January 16, 2025.

The predicate device has not been subject to a design-related recall.

## Device Description

The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection is a wearable infusion pump designed to deliver Remodulin® (treprostinil) subcutaneously for the treatment of pulmonary arterial hypertension (PAH). Remodulin® was FDA-approved under NDA 021272. The system consists of several components: a wearable pump assembly, a remote interface, 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 system to the patient. The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection is prescription use only.

The pump assembly is composed of a durable pump and a disposable, single-use cassette with a user-filled drug reservoir. The pump 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 subject system utilizes a micro-dosing pump mechanism supplemented with acoustic volume sensor feedback to ensure delivery accuracy.

The subject device has updated branding and also modifies the predicate device to be used with an additional infusion set.

## Indications for Use

The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection (the RemunityPRO system) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older.

## 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 (K241736) | Subject Device | Equivalence |
|---|---|---|---|
| Device Classification Regulation and Product Code | Class II Infusion Pump<br>21 CFR 880.5725<br>Product Code: FRN | Class II Infusion Pump<br>21 CFR 880.5725<br>Product Code: FRN | **No change** |
| Indications for Use | The Remunity® 2.0 Pump for Remodulin® (treprostinil) Injection (the Remunity 2.0 System) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older. | The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection (the RemunityPRO system) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older. | **No change** |
| Prescription Use or Over the Counter (OTC) | Prescription | Prescription | **No change** |
| Intended Patient Population | Age 17 years and older | Age 17 years and older | **No change** |
| Patient Environment | On-body wearable ambulatory pump | On-body wearable ambulatory pump | **No change** |

The intended use and indications for use remain unchanged in the subject device with respect to the predicate device (K241736).

## *Technological Characteristic Comparison*

The table below compares the updates made to the subject device as compared to the predicate device and includes an assessment of these updates in the context of safety and effectiveness.

| **Characteristic** | **Predicate Device (K241736)** | **Subject Device** | **Equivalence** |
|---|---|---|---|
| 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<br>(2.4 in x 2.4 in x 0.4 in) | 6 cm x 6 cm x 2 cm<br>(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 | 8 µL/hr – 225 µL/hr, with increments of 1 µL/hr | 8 µL/hr – 225 µL/hr, with increments of 1 µL/hr | **No change** |
| Basal Accuracy | ±6% | ±6% | **No change** |
| Bolus Volume after Occlusion Release | < 8 µL at all rates | < 8 µL at all rates | **No change** |
| Time to Occlusion Alarm | Maximum time to occlusion alarm:<br>• ≥ *100 µL/hr:* 12 minutes<br>• < *100 µL/hr:* 8 hours | Maximum time to occlusion alarm:<br>• ≥ *100 µL/hr:* 12 minutes<br>• < *100 µL/hr:* 8 hours | **No change** |
| Material Biocompatibility | *Fluid contacting:* Polycarbonate (PC), COP, Bromobutyl, SEBS, Polyurethane<br><br>*Patient contacting:* PC, Acrylic, Polyurethane, ABS, Aluminum | *Fluid contacting:* Polycarbonate (PC), COP, Bromobutyl, SEBS, Polyurethane<br><br>*Patient contacting:* PC, Acrylic, Polyurethane, ABS, Aluminum | **No change** |
| Cassette Shelf Life | 2 years | 2 years | **No change** |
| Service Life | 3 years | 3 years | **No change** |
| Applicable Safety Standards | • IEC 60601-1<br>• IEC 60601-1-2<br>• IEC 60601-1-8<br>• IEC 60601-1-11<br>• IEC 60601-2-24<br>• ISO 11137-1 (Sterilized via Gamma Radiation)<br>• ISO 10993-1<br>• ISO 14971<br>• IEC 60601-4-2<br>• ANSI C63.27<br>• AIM 7351731 | • IEC 60601-1<br>• IEC 60601-1-2<br>• IEC 60601-1-8<br>• IEC 60601-1-11<br>• IEC 60601-2-24<br>• ISO 11137-1 (Sterilized via Gamma Radiation)<br>• ISO 10993-1<br>• ISO 14971<br>• IEC 60601-4-2<br>• ANSI C63.27<br>• AIM 7351731 | **No change** |
| Power Source | Rechargeable Lithium Ion Battery | Rechargeable Lithium Ion Battery | **No change** |

| Characteristic | Predicate Device (K241736) | Subject Device | Equivalence |
|---|---|---|---|
| Pump Storage Conditions | • Temperature: -25 °C to 70 °C (-13 °F to 158 °F)<br>• Non-condensing humidity: up to 90%<br>• Pressure: 50 kPa to 106 kPa | • Temperature: -25 °C to 70 °C (-13 °F to 158 °F)<br>• Non-condensing humidity: up to 90%<br>• Pressure: 50 kPa to 106 kPa | **No change** |
| Operating Conditions | • Temperature: 5 °C to 40 °C (41 °F to 104 °F)<br>• Non-condensing humidity: up to 90%<br>• Pressure: 70 kPa to 106 kPa | • Temperature: 5 °C to 40 °C (41 °F to 104 °F)<br>• Non-condensing humidity: up to 90%<br>• 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** |
| Battery Operating Time | • 72 hours | 72 hours | **No change** |
| Infusion Set | • Medtronic Quick-set Infusion Set: 23 in (58 cm), MMT-392, MMT-393 [K991759]<br>• Medtronic Silhouette Infusion Set: 23 in (58 cm), MMT-373 [K162812]<br>• Smiths Medical Cleo 90 Infusion Set: 24 in (61 cm), 21-7230-24, 21-7220-24 [K042172] | • Medtronic Quick-set Infusion Set: 23 in (58 cm), MMT-392, MMT-393 [K991759]<br>• Medtronic Silhouette Infusion Set: 23 in (58 cm), MMT-373 [K162812]<br>• Smiths Medical Cleo 90 Infusion Set: 24 in (61 cm), 21-7230-24, 21-7220-24 [K042172]<br>• **Neria Guard Infusion Set, 23in (58 cm), 704060-5226, 704060-5229 [K192647]** | **Equivalent**<br><br>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 the previous clearance (K241736). |
| Cassette | Unity 2.0 Cassettes, 3 mL, user-filled | Unity 2.0 Cassettes, 3 mL, user-filled | **No change** |
| Priming Method | Primed by Pump after Cassette attachment to the Pump | Primed by Pump after 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 RemunityPRO™ Pump for Remodulin® (treprostinil) Injection 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 different questions of safety or effectiveness. The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection is substantially equivalent to the predicate Remunity® 2.0 Pump for Remodulin® cleared under K241736.