January 16, 2025

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

Re: K241736
Trade/Device Name: Remunity® 2.0 Pump for Remodulin® (treprostinil) Injection
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: December 18, 2024
Received: December 18, 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,

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)*
K241736

Device Name
Remunity® 2.0 Pump for Remodulin® (treprostinil) Injection

Indications for Use *(Describe)*
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.

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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K241736 510(k) Summary

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

Submitter Information

510(k) Sponsor	DEKA Research and Development Corp. 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 10, 2025

Proposed Device

Common/Usual Name:	Infusion Pump
Trade/Proprietary Name:	Remunity® 2.0 Pump for Remodulin® (treprostinil) Injection
Classification Name:	Infusion pump
Device Classification:	880.5725
Product Code:	FRN
Class:	II
Device Panel:	General Hospital

Predicate Device

Unity Subcutaneous Delivery System for Remodulin®, K190182

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

Reference Devices

The cassette and pump hardware of the subject system are identical to those of the reference device, the DEKA ACE Pump System cleared on March 13, 2024 under K233952.

The remote interface hardware of the subject system is identical to that of the reference device, the Remunity System which was previously cleared under premarket application K240256 on June 12, 2024.

Device Description

The Remunity 2.0 System 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 Remunity 2.0 System 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.

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.

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 (K190182)**	**Subject Device**	**Equivalence**
Device Classification Regulation and Product Code	Class II Infusion Pump 21 CFR 880.5725 Product Code: FRN	Class II Infusion Pump 21 CFR 880.5725 Product Code: FRN	**No change**
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).	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.	**Equivalent** Both devices are labeled specifically for use with Remodulin. The subject system has a widened indicated patient population age range in order to align with the indications for Remodulin.
Prescription Use or Over the Counter (OTC)	Prescription	Prescription	**No change**
Intended Patient Population	Greater than 22 years of age	Age 17 years and older	**Equivalent** The subject system has a widened indicated patient population age range, in alignment with the Remodulin indications.
Patient Environment	On-body wearable ambulatory pump	On-body wearable ambulatory pump	**No change**

The intended use remains unchanged in the subject device with respect to the predicate device (K190182). The indications for use have been updated expand the indicated patient population, in alignment with Remodulin drug labeling. This update has been verified through bench performance testing and validated through human factors testing.

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 (K190182)**	**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 (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	8 µL/hr – 225 µL/hr, with increments of 1 µL/hr	**Equivalent** The basal delivery rate range for the subject system is wider than that of the predicate, but remains in alignment with the Remodulin prescribing information. Bench testing, including delivery accuracy and occlusion detection, demonstrates equivalent performance for the expanded flow rate range. No additional risks.
Basal Accuracy	±6%	±6%	**No change**

Characteristic	**Predicate Device (K190182)**	**Subject Device**	**Equivalence**
Bolus Volume after Occlusion Release	< 40 µL at all rates	< 8 µL at all rates	**Equivalent** The subject system demonstrates improved post-occlusion bolus volume performance compared to the predicate device. No additional risks.
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**
Material Biocompatibility	*Fluid contacting:* Polycarbonate (PC), Bromobutyl, SEBS, Polyurethane *Patient contacting:* PC, Acrylic, Polyurethane, ABS, Aluminum, PC-ABS	*Fluid contacting:* Polycarbonate (PC), COP, Bromobutyl, SEBS, Polyurethane *Patient contacting:* PC, Acrylic, Polyurethane, ABS, Aluminum	**Equivalent** The materials of the subject device meet the same biocompatibility standards as the predicate device. No additional risks.
Cassette Shelf Life	2 years	2 years	**No change**
Service Life	3 years	3 years	**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 • IEC 60601-4-2 • ANSI C63.27 • AIM 7351731	**Equivalent** The subject device complies with additional safety standards. No additional risks.
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	**No change**

Characteristic	**Predicate Device (K190182)**	**Subject Device**	**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	Push-Button Device	Touchscreen Device	**Equivalent** The subject Remote Interface has identical hardware and functionality to the reference device (K240256). No additional risks.
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] • Medtronic Silhouette Infusion Set: 23 in (58 cm), MMT-373 [K162812] • 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] • Medtronic Silhouette Infusion Set: 23 in (58 cm), MMT-373 [K162812] • Smiths Medical Cleo 90 Infusion Set: 24 in (61 cm), 21-7230-24, 21-7220-24 [K042172]	**No change**

Characteristic	**Predicate Device (K190182)**	**Subject Device**	**Equivalence**
Cassette	Remodulin Unity Cassettes, 3 mL, user-filled	Unity 2.0 Cassettes, 3 mL, user-filled	**Equivalent** The subject Cassette is identical to the reference device Cassette (K233952). The updated design removes the filling aid present in the predicate Cassette. Workflows associated with removal of the filling aid were validated through human factors testing. No additional risks.
Priming Method	Manually primed by user before Cassette attachment to the Pump	Primed by Pump after Cassette attachment to the Pump	**Equivalent** Human factors and bench testing demonstrates that the updated prime method is safe and effective. No additional risks.

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 were evaluated: • Delivery accuracy • Occlusion performance • Fault Insertion • Drug stability and particulate • Incidental delivery performance • Remodulin exposure • Battery performance • Durability • Shipping and Storage

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 validation 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, AIM 7351731
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 subject system was specified and developed by DEKA. DEKA complies with the FDA Quality System Regulation as specified in 21 CFR Part 820, as well as to ISO 13485.

Conclusion

The differences between the predicate and the subject device do not raise different questions of safety or effectiveness. The Remunity 2.0 System is substantially equivalent to the Unity Subcutaneous Delivery System for Remodulin® cleared under K190182.