



July 24, 2026

Deka R&D Corp
Paul Smolenski
Regulatory Affairs
340 Commercial St.
Manchester, New Hampshire 03101

Re: K253703

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: June 22, 2026
Received: June 23, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K253703

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.

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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
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Manchester, NH 03101

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Date Prepared July 23, 2026

Subject 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 RemunityPRO™ Pump for Remodulin® (treprostinil) Injection, K250357, cleared on March 11, 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). The system consists of several components: a wearable pump assembly, a paired device, and accessories (e.g., rechargeable batteries, battery charger, charging cable, power adapter). The user interface for the system is the RemunityPRO+ app downloaded onto the user's mobile device. 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 for 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 added the ability to perform over-the-air software updates.

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 table below compares the intended use of the Subject and Predicate Devices.

Characteristic	Predicate Device (K250357)	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 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.	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 (K250357).

Technological Characteristic Comparison

The table below compares the updated Subject Device with the Predicate Device and includes an assessment of the updates in the context of safety and effectiveness.

Characteristic	Predicate Device (K250357)	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

Characteristic	Predicate Device (K250357)	Subject Device	Equivalence
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
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
Delivery Rate 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: ≥ 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	<i>Fluid contacting:</i> Polycarbonate (PC), COP, Bromobutyl, SEBS, Polyurethane <i>Patient contacting:</i> PC, Acrylic, Polyurethane, ABS, Aluminum	<i>Fluid contacting:</i> Polycarbonate (PC), COP, Bromobutyl, SEBS, Polyurethane <i>Patient contacting:</i> 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 - 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	- 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	No change
Power Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	No change
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

Characteristic	Predicate Device (K250357)	Subject Device	Equivalence
Paired Interface	Touchscreen Device (Manufacturer provided remote interface & App)	Touchscreen Device (Manufacturer provided remote interface & App or User provided mobile device for RemunityPRO+ App)	Similar Predicate and Subject paired interfaces are similar sized handheld touch screens. The visual format of the Predicate and Subject Device's user interface screens are the same. There is no change to clinical performance. There are no new questions of safety or effectiveness.
System User Feedback	Visual, audible, vibratory	Visual, audible, vibratory	No change
Cloud Communication	No Cloud Connection	2-way Cloud Communication - Secure Pairing - Pump Software Updates - Data collected for trouble shooting and failure analysis	Similar No change to clinical performance. Cloud communication adds secure pairing functionality to ensure unique pump registration to support the BYOD use model. Predicate Device logs device data on pump. Subject Device logs data on pump and transmits it to the cloud. Subject Device can perform over-the-air software updates. Cybersecurity controls added to accommodate BYOD use model.
Battery Operating Time	72 hours	72 hours	No change

Characteristic	Predicate Device (K250357)	Subject Device	Equivalence
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] - Neria Guard Infusion Set, 23in (58 cm), 704060-5226, 704060-5229 [K192647]	- 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] - Neria Guard Infusion Set, 23in (58 cm), 704060-5226, 704060-5229 [K192647]	No Change
Cassette	3 mL user-filled cassettes	3 mL user-filled cassettes	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 testing was conducted to verify device performance and 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 new or different questions of safety or effectiveness. The RemunityPRO+ Pump for Remodulin (treprostinil) Injection is substantially equivalent to the predicate RemunityPRO Pump for Remodulin cleared under K250357.