DEKA Research & Development
Jason Demers
Project Manager
340 Commercial Street
Manchester, New Hampshire 03101

Re: K191313
Trade/Device Name: Unity Subcutaneous Infusion System for Remodulin
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: QJY
Dated: May 14, 2019
Received: May 15, 2019

Dear Jason Demers:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Nikhil Thakur
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191313

Device Name
Unity Subcutaneous Delivery System for Remodulin®

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

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.

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510(K) SUMMARY – K191313

Submitter Information

510(k) Sponsor:	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person	Jason Demers Program Manager DEKA Research & Development Corporation Phone: (603) 669-5139 Fax: (603) 624-0573 jdemers@dekaresearch.com
Date Prepared:	February 21, 2020

Proposed Device

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

Predicate Device

Unity Subcutaneous Delivery System for Remodulin® K190182.
No reference devices are used in this submission.

Device Description

The Unity Subcutaneous Delivery System for Remodulin® (Unity 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 Unity 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 subcutaneous delivery of Remodulin from the Unity System to the patient.

The pump assembly is composed of a reusable pump and a disposable single-use cassette 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 Unity System utilizes a micro-dosing pump mechanism supplemented with acoustic volume sensor feedback to ensure delivery accuracy.

Cassettes are identical to those cleared under K190182, with the exception that the specialty pharmacy will take the cassettes out of their sterile packaging, cap the outlet of the cassette and aseptically fill the cassette reservoir through the cassette filling septum following USP 797 Compounding Sterile Preparations. The specialty pharmacy will then package

these filled cassettes and ship to the intended end user under controlled conditions outlined in the labeling. The pharmacy-filled cassette is intended to be stored (inclusive of shipping item) up to 14-days and is intended to be in use for up to 72-hours.

The device is prescription use only.

Indications for Use

The Unity Subcutaneous Infusion System (the Unity System) is intended for continuous subcutaneous delivery of Remodulin® (treprostinil) Injection for use in adults (greater than 22 years of age).

Substantial Equivalence Discussion

Intended Use Comparison

The table below includes a comparison of the intended use between the new device and those of the predicate device:

Characteristic	**Predicate** Unity Subcutaneous Delivery System for Remodulin® K190182	**Proposed** Unity Subcutaneous Delivery System for Remodulin® K191313
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).	No Change
Prescription Only or Over the Counter	Prescription Only	No Change
Intended Population	Adults (>22 years of age)	No Change
Environment of Use	In professional healthcare facility and home healthcare environments	No Change

Discussions of differences in Indications for Use statement

The indications for use statement for the subject device is identical to the predicate device cleared under K190182.

Discussions of differences in intended population

The intended population is for the subject device is identical to the predicate device cleared under K190182.

The Unity system is indicated for adults (greater than 22 years of age)

Discussions of differences in environment of use

The environment of use for the subject device is identical to the predicate device cleared under K190182.

Comparison of Technological Characteristics with the Predicate Device

Table 1 compares the characteristics of the predicate device to the proposed device and includes an assessment of differences between them and why the difference between the subject device and predicate device do not introduce new or different questions of safety and effectiveness.

Table 1. Comparison of Predicate and Proposed Devices

Characteristic	**Predicate** Unity Subcutaneous Delivery System for Remodulin® K190182	**Proposed** Unity Subcutaneous Delivery System for Remodulin®	Discussion of Differences
Mechanism of action	Microprocessor controlled Micro- dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy.	Same	N/A
Infusion Accuracy	±6%	Same	N/A
Maximum Infusion pressure	<16.4 psi (<113 kPa)	Same	N/A
Programmable Flow rate ranges	16 µl/hr to 225 µl/hr with increments of 1 µl/hr	Same	N/A
Time to occlusion alarm	Maximum time to occlusion alarm: <12 min. at rates ≥ 100 µl/hr within 8 hr, at rates < 100 µl/hr	Same	N/A
Post-occlusion bolus	<40 µl at all rates.	Same	N/A

Characteristic	**Predicate** Unity Subcutaneous Delivery System for Remodulin® K190182	**Proposed** Unity Subcutaneous Delivery System for Remodulin®	Discussion of Differences
Alarms & Alerts	• Battery depleted • Battery Low (pump) • Battery Low (remote) • Cassette Depleted • Cassette Problem • Cassette Removed • Depletes Soon • Pump Error • Pump Failure • Occlusion • Delivery Stopped • Basal Not Started • Idle • Software Version Error • Tech • Excessive Noise • No Communication • Message Timeout • Pairing Failed Walkaway	Same	N/A
Device Service Life	3 years	Same	N/A
Dimensions & Weight	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in) 50 g (1.76 oz)	Same	N/A
Materials	*Cassette fluid path*: Polycarbonate, Bromobutyl, SEBS, polyurethane *Pump*: ABS, Polycarbonate, Aluminum *Cartridge*: Polycarbonate, Acrylic, polyurethane Filling Aid: PC-ABS	Additional Materials include: *Cap:* Polycarbonate	The new component utilized the same materials used in the predicate and did not introduce new biocompatibility issues. Performance was evaluated to be substantially equivalent.

Characteristic	**Predicate** Unity Subcutaneous Delivery System for Remodulin® K190182	**Proposed** Unity Subcutaneous Delivery System for Remodulin®	Discussion of Differences
Environment of Use	In professional healthcare facility and home healthcare environments	Same	N/A
Ingress protection	IP58 when connected to the reservoir	Same	N/A
Power source	Rechargeable Lithium-Ion Battery	Same	N/A
Storage Conditions	Temperature: -13˚F to 158˚F (-25˚C to 70˚C) Non-condensing humidity: up to 90%. Pressure: 500 hPa to 1060 hPa	Same	N/A
Operating Conditions	Temperature: 41˚F to 104˚F (5˚C to 40˚C) Non-condensing humidity: up to 90% Pressure: 700 hPa to 1060 hPa	Same	N/A
Remote user feedback	Audible, vibratory	Same	N/A
Administration Set	Medtronic Quick-set Infusion Set Medtronic Silhouette and Infusion Set Smiths Medical Cleo 90 Infusion Set	Same	N/A
Cassette	Remodulin Unity cassettes, 3 ml, User filled	Remodulin Unity cassettes, 3 ml, Specialty Pharmacy filled	Cassettes are filled by Specialty Pharmacist and are appropriate for the design of the infusion pump.
Expiration – Cassette	User Fill, 6 Months from date of manufacture	Pharmacy-Fill, 14 Days	The differences in cassette expiration were evaluated through container closure integrity, antimicrobial effectiveness and stability testing.

Characteristic	**Predicate** Unity Subcutaneous Delivery System for Remodulin® K190182	**Proposed** Unity Subcutaneous Delivery System for Remodulin®	Discussion of Differences
End User Packaging -	Unfilled cassette without luer lock fluid path closure, placed in vacuum formed tray with Tyvek lid and then Gamma sterilized	Aseptically filled cassette with female luer lock fluid path closure, placed in plastic clamshell tray and sealed in foil pouch	The predicate device provides a terminally sterilized unfilled cassette inside the sterile barrier provided by the vacuum formed tray and Tyvek lid. The pharmacy-filled cassette provides a closed fluid pathway that was terminally sterilized prior to being aseptically filled and repackaged. The differences in packaging were evaluated through performance, sterility, container closure integrity and ingress testing.

Non-Clinical/ Performance Testing:

The following performance data/non-clinical testing was provided in support of the substantial equivalence determination for the Unity System.

A safety assurance case was provided for the Unity Subcutaneous Delivery System for Remodulin, as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle.

The stated goal of the safety assurance case is: "The Unity Remodulin Subcutaneous Infusion System is adequately safe for its intended use."

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The context for the assurance case was updated to reflect the new use scenario of pharmacy filled cassettes. The supporting assurance arguments covered the following attributes:

- All hazards associated with the system have been identified and adequately addressed
- Device reliability is adequate
- The device design requirements are adequately verified and validated

The arguments were updated from the original assurance case presented in predicate, K190182, to reflect new hazards and requirements associated with the changes.

The following specific evidence was included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices.

Since the assurance case builds on the original case, only evidence used to provide assurance related to the changes is listed here:

Accessory compatibility	• Verification of the pump essential performance was completed with labeled administration sets
Device performance	• The essential performance requirements of the device were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle" • Performance of the device to maintain adequate assurance of drug stability, and protection from microbial ingress was evaluated through drug stability studies, container closure integrity and antimicrobial effectiveness testing. The testing was done to represent 14 days + 72 hours of in-use at a minimum.
Human Factors	• Human factors evaluation per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016).
Reprocessing, Cleaning, Sterility	• ISO 11137-1:2006 + A1:2013 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices • ISO 11607-1:2006 + A1:2014 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems Validation per the FDA Guidance for Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015) confirmed cleaning and disinfection instruction provided in instructions for use
Biocompatibility	• The materials used for the Unity System comply with biocompatibility requirements outlined in ISO 10993-1:2009 and the Guidance for Industry and Food and Drug Administration Staff, *Use of International Standard ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process* are considered to be biocompatible.

Clinical Study

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

Conclusion

The modifications to the Unity System Operator's User Manual and the end user packaging to include the option for the cassettes to be filled with Remodulin by the Specialty Pharmacy as a user convenience does not change the intended use of the subject device compared to the Unity System cleared under premarket notification K190182. The changes summarized in this submission do not raise different questions of safety and effectiveness.

The performance of the device is supported by the assurance case, non-clinical testing and risk management activities. The Unity Subcutaneous Delivery System for Remodulin is Substantially Equivalent (SE) to the Unity Subcutaneous Delivery System for Remodulin cleared under premarket notification K190182.