May 6, 2019
DEKA Research & Development
Brian Carney
Project Regulatory Affairs Manager
340 Commercial Street
Manchester, New Hampshire 03101

Re: K190182
Trade/Device Name: Unity Subcutaneous Delivery System for Remodulin
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN
Dated: January 31, 2019
Received: February 1, 2019

Dear Brian Carney:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Tina Kiang, Ph.D
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)*
K190182

Device Name
Unity Subcutaneous Delivery System for Remodulin®

Indications for Use *(Describe)*
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).

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."

510(K) SUMMARY – K190182

Submitter Information

510(k) Sponsor:	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person	Brian Carney Project Regulatory Affairs Manager DEKA Research & Development Corporation Phone: (603) 669-5139 Fax: (603) 624-0573 bcarney@dekaresearch.com
Date Prepared:	May 3, 2019

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:	FRN
Class	II
Device Panel:	General Hospital Devices Branch

Predicate Device

CADD-MS3 Ambulatory Infusion Pump (Smiths Medical) K051568.
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 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 with a 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 Unity System utilizes a micro-dosing pump mechanism supplemented with acoustic volume sensor feedback to ensure delivery accuracy.

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** CADD-MS 3 Ambulatory Infusion Pump K051568	**Proposed** Unity Subcutaneous Deliver System for Remodulin® K190182
Indications for Use	The CADD-MS 3 Ambulatory Infusion Pump is designed for subcutaneous, intravenous, epidural and intrathecal infusion of medication. The Smiths Medical MD, Inc, 3-ml Cartridge Reservoir is designed for use with the CADD-MS 3 for delivering medication	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).
Prescription Only or Over the Counter	Prescription Only	Prescription Only
Intended Population	Not Specified	Adults (>22 years of age)
Environment of Use	In hospital or out-patient settings	In professional healthcare facility and home healthcare environments

Discussions of differences in Indications for Use statement

The indications for use statement for the Unity System is not identical to the predicate device. The predicate is indicated for four different delivery types, including subcutaneous delivery, whereas the Unity System limits delivery to subcutaneous infusion. Additionally, the predicate device does not specify a particular drug or set of drugs. The Unity System is labeled only for use with Remodulin. The Unity System's indications is a specific subset of the predicate device's indications for use and is therefore not a new intended use. Additionally, compatibility with Remodulin specifically has been verified through performance testing.

Discussions of differences in intended population

The Unity system is indicated for adults (greater than 22 years of age) whereas the predicate does not specify an indicated age group. The age group for the subject device was validated in the Human Factors testing.

Discussions of differences in environment of use

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

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 Device K051568	Subject Device K190182	Discussion of Differences
Mechanism of action	Microprocessor based electronic syringe pump	Microprocessor controlled Micro- dosing pump mechanism supplemented with acoustic volume sensor (AVS) feedback for monitoring delivery accuracy.	AVS technology provides accuracy confirmation of the volume of fluid delivered. This was supported with clinical and non-clinical testing.
Infusion Accuracy	±3% (nominal).	±6%	Compliant with Remodulin USPI an infusion accuracy of ±6% satisfies the Remodulin delivery accuracy requirement for administration by subcutaneous injection
Maximum Infusion pressure	23 psi (159 kPa)	<16.4 psi (<113 kPa)	The maximum infusion pressure is less that the predicate; however, the infusion accuracy was verified through performance testing and validated to be appropriate for the intended use.
Programmable Flow rate ranges	0.000 mL/hr to 1.000 mL/hr with increments of .002 mL/hr	16 µl/hr to 225 µl/hr with increments of 1 µl/hr	Infusion accuracy was maintained within specification across flow rates that span the programmable flow rates of the device through bench testing and is appropriate based on the intended use.
Time to occlusion alarm	Maximum time to occlusion alarm: 12 min. to 15 min. at 124 µl/hr (intermediate rate) 9.5 hr. to 19 hr. at 2 µl/hr (minimum rate)	Maximum time to occlusion alarm: <12 min. at rates ≥ 100 µl/hr within 8 hr, at rates < 100 µl/hr	Time to occlusion is similar to the predicate. Differences were evaluated through a risk based approach to be appropriate for the intended use.
Post-occlusion bolus	At minimum rate: approximately 40 µl	<40 µl at all rates.	The range for the Unity System is tailored for the delivery of Remodulin. These differences do not raise different questions

Characteristic	Predicate Device K051568	Subject Device K190182	Discussion of Differences
	at intermediate rate: approximately 210 µl		of safety and effectiveness and have been verified through performance testing.
Alarms & Alerts	• Battery depleted • Battery low • Blockage detected • Cartridge empty • Cartridge removed • Cartridge very low • Depletes soon • Edit not saved • Key stuck • Program defaulted • Pump stopped • Site change reminder • System fault	• 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	Alarms were validated based on the intended use of the device and the unique technological characteristics.
Device Service Life	Not stated	3 years	The device was evaluated through performance testing to meet the essential performance throughout the service life.
Dimensions & Weight	3.2 in x 1.8 in x 0.95 in Approximately 3.2 oz including battery and cartridge	6 cm x 6 cm x 2 cm (2.4 in x 2.4 in x 0.4 in) 50 g (1.76 oz)	The devices are similar in size and intended to be ambulatory.
Materials	Cartridge: Polypropylene (plunger and other materials unknown)	*Cassette fluid path*: Polycarbonate, Bromobutyl, SEBS, polyurethane *Pump*: ABS, Polycarbonate, Aluminum *Cartridge*: Polycarbonate, Acrylic, polyurethane	The appropriate biocompatibility and toxicology testing has been conducted on all materials found in the fluid path. Non-clinical testing supported the differences in materials. The differences in the materials do not raise different questions of safety and effectiveness.

Characteristic	Predicate Device K051568	Subject Device K190182	Discussion of Differences
		Filling Aid: PC-ABS	
Environment of Use	In hospital or out-patient settings	In professional healthcare facility and home healthcare environments	Same
Ingress protection	IPX8 when pump's labels and outer shell are intact	IP58 when connected to the reservoir	The Unity System provides protection against particle ingress in addition to moisture protection. This is appropriate based on the intended use of the device.
Power source	1 AAA alkaline battery	Rechargeable Lithium-Ion Battery	The differences were evaluated through performance testing; Lithium-Ion Battery complies with IEC 62133.
Storage Conditions	Temperature: -4°F to 140°F (-20°C to 60°C) Non-condensing humidity: up to 90% Pressure: 700 hPa to 1060 hPa	Temperature: -13˚F to 158˚F (-25˚C to 70˚C) Non-condensing humidity: up to 90%. Pressure: 500 hPa to 1060 hPa	The differences in storage conditions were evaluated through performance testing.
Operating Conditions	Temperature: 35.6°F to 104°F (2°C to 40°C) Non-condensing humidity: up to 90% Pressure: 700 hPa to 1060 hPa	Temperature: 41˚F to 104˚F (5˚C to 40˚C) Non-condensing humidity: up to 90% Pressure: 700 hPa to 1060 hPa	The operating conditions are similar. The differences in operating conditions were evaluated through performance testing.
Accessories			
Remote user feedback	Audible, vibratory	Audible, vibratory	Same
Administration Set	Unomedical Comfort Infusion Set	Medtronic Quick-set Infusion Set Medtronic Silhouette and Infusion Set Smiths Medical Cleo 90 Infusion Set	Similar; compatibility testing was completed to verify use with the designated infusion sets
Cartridge	Smiths Medical, Inc. 3 ml Medication Cartridge,	Remodulin Unity cassettes, 3 ml, User filled	Both cartridges can be user filled and are appropriate for the design of the infusion pump.

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 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 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:

Software & Cybersecurity	• Software documentation is included according to FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* for Major level of concern for the software embedded in the Unity System. • Software validation was conducted according to IEC 62304 and the FDA guidance document *General Principles of Software Validation – Final Guidance for Industry and FDA Staff*. • Cybersecurity risks were assessed and documentation is included based on the FDA's *Guidance of Premarket Submissions for Management of Cybersecurity in Medical Device.* • AAMI ANSI IEC 62304:2006 Medical Device Software – Software Life Cycle Process
Electrical Safety	• AAMI/ANSI ES 60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R) 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EMC	• IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1: General Requirements for Safety-2-Collateral Standard: Electromagnetic Compatibility-Requirements & Tests
Wireless Coexistence & RF Wireless testing	• FDA Guidance Document "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" • ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
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"
Battery testing	• Li-ion battery safety successfully tested per IEC 62133
Human Factors	• Human factors studies per the FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016). The human factors studies were conducted with the intended user population, use environment and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
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* and are considered to be biocompatible. • Testing was conducted for cytotoxicity, sensitization, irritation, pyrogenicity, and hemolysis. The acute systemic toxicity, subchronic systemic toxicity, and genotoxicity endpoints were addressed through the extractables/leachables study with a toxicological risk assessment. • AAMI ST72: 2011 Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing • USP 39 <788>:2016 Particulate Matter in Injections

Clinical Testing

A clinical study was conducted to support the substantial equivalence of the device and to clinically validate the Acoustic Volume Sensor (AVS) design. The *Performance Assessment of The Unity Infusion System with 0.9% Sodium Chloride Injection in Healthy Volunteers* study was conducted to establish evidence that the AVS measurement process consistently produces results within an acceptable, predetermined measurement uncertainty. All participants were healthy subjects between 18 and 55 years of age, inclusive, at the time of informed consent.

Objective

The objective of this study was to assess the performance of the Unity System to deliver 0.9% sodium chloride (normal saline [NS]) by subcutaneous (SC) infusion to healthy volunteers by assessing the following:

- In vivo infusion delivery accuracy assessed by measured volumetric flow rate compared to programmed flow rate of the Unity System to demonstrate environmental noise of other elements of daily use interfered with the ability of the Unity System to deliver accurately when participants were challenged to loud sound exposures.
- In vivo the Unity System reliability assessed by device history logs (flow rate, malfunction, complications, etc.) and subject diaries (environmental exposures)

Criteria for Evaluation

Pump Performance: In vivo infusion delivery accuracy was assessed by measured volumetric flow rate compared to programmed flow rate of the Unity System. In vivo Unity System reliability was assessed by device history logs (flow rate, malfunction, complications, etc.) and subject diaries (environmental exposures).

Safety: Per protocol, all adverse events (AEs), serious adverse events (SAEs), and unanticipated adverse device effects (UADEs) were to be documented from Baseline until the subject was either discontinued from the study or all End of Infusion study assessments were complete. All AEs associated with a device complication were to be investigated.

Conclusions

Pump Performance: The study successfully demonstrated that the majority of measured data fell within the accuracy specification. There were brief intervals (less than six hours) where the flow rate measured was outside the performance specification limit for under delivery (-6%). Each of these intervals were within the measurement uncertainty of the measure equipment used in the study or associated with the delivery of air bubbles, and all were within 25%. The study found no evidence of environmental noise or other elements of daily use interfered with the ability of the Unity System to deliver accurately.

Safety: No safety concerns related to use of the Unity System were identified during this study.

Conclusion

Differences between the intended use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing, clinical testing, and risk management activities. The Unity Subcutaneous Delivery System for Remodulin is Substantially Equivalent (SE) to the CADD-MS 3 Ambulatory Infusion Pump, cleared under K051568.