May 17, 2024

Zevex, Inc.
Christopher Dodge
Director, Quality Assurance & Regulatory Affairs
4314 Zevex Park Lane
Salt Lake City, Utah 84123

Re: K232793
Trade/Device Name: Curlin 8000 Ambulatory Infusion System; Enterprise Solution (ES) Software; Curlin 380-Series Adminstration Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN
Dated: April 17, 2024
Received: April 17, 2024

Dear Christopher Dodge:

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.

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

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)*
K232793

Device Name
Curlin 8000 Ambulatory Infusion System;
Enterprise Solution (ES) Software;
Curlin 380-series Administration Sets

Indications for Use *(Describe)*
The CURLIN® 8000 ambulatory infusion pump system is indicated for use in home care and clinical settings for the controlled administration of prescribed medical fluids through clinically accepted routes of administration: intravenous, intra-arterial, subcutaneous, epidural, and perineural, to adult patients. The CURLIN® 8000 is not intended for use on pediatric patients. The pump is intended to deliver a variety of therapies (drugs and fluids) which have been approved for these routes of administration. Examples of the therapies, which may be delivered using the CURLIN® 8000 pump, include hydration, parenteral nutrition, anti-infectives, pain management, inotropes, chemotherapy, immune globulin, and biologics. The CURLIN 8000 is not indicated for the delivery of cellular blood products.

RxManager Enterprise Solution Software allows the user to create and manage pump configurations and therapy-based protocols to be used with the Curlin 8000 Ambulatory Infusion Pump.

Curlin Administration Sets are intended to be used with Curlin infusion pumps to deliver medication from a container to a patient.

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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K232793 510(k) Summary

Date: May 16, 2024

I. SUBMITTER

Zevex, Inc.
4314 Zevex Park Lane
Salt Lake City, Utah 84123

Telephone: (801) 264-1001
Fax: (801) 264-1051

Contact Person:

Christopher Dodge
Director, Quality Assurance & Regulatory Affairs
Cell Phone: (801) 560-7147

II. DEVICE

Proprietary / Trade Name: CURLIN® 8000 Ambulatory Infusion System with Rx Manager Enterprise Solution Software
Common Name: Infusion Pump
Classification Name: Pump, Infusion (21 CFR 880.5725)
Regulatory Class: II
Product Code: FRN

Proprietary / Trade Name: CURLIN® Administration Sets
Common Name: Intravascular Administration Sets
Classification Name: Set, Administration, Intravascular (21 CFR 880.5440)
Regulatory Class: II
Product Code: FPA

III. PREDICATE DEVICE

CADD®-Solis VIP Model 2120 (K111275) with CADD™-Solis Medication Safety Software

CADD® Administration Sets (K170982)

IV. DEVICE BRIEF DESCRIPTION

The CURLIN® 8000 Ambulatory Infusion Pump is a small, compact and light weight infusion delivery device that utilizes a curvilinear peristaltic pumping mechanism similar is design to the CADD®-Solis VIP Model 2120 but curvilinear to allow the pump to be more compact. The user activates the CURLIN® 8000 pump via a color LCD screen and keypad user interface. Commands are issued to the microprocessor by activating the user interface. Microprocessor actions are controlled by a program, which is contained in the pump's memory.

The CURLIN® 8000 pump consists of components such as the user interface, sensors, communication ports, power ports, structural (housing) components, electronics, pumping mechanism, watchdog timer, pump battery and circuitry, real time clock, on-board memory, and pump log. Exterior surface components include the pump housing, platen (door assembly), LCD lens, keypad, and labels. Materials used for the construction of these components are widely used within the medical industry.

The CURLIN® 8000 pump is designed to deliver measured drug therapy to patients in homecare, infusion suites, oncology and other alternate site locations as appropriate. The pump also has applicability in the acute care market specifically in small hospitals (300 beds or less), Labor and Delivery Units, and other areas of the hospital where pain management is required.

The CURLIN® 8000 pump is designed to be used with CURLIN® 380-series administration sets, which provide a sterile pathway for the delivery of the infusate fluid from the infusion container (e.g., IV reservoir bag) to the distal connection, which connects to the patient's catheter / delivery site.

The Rx Manager Enterprise Solution (ES) pharmacy application, which consists of the Rx Manager, Admin Manager and Service Manager, incorporates a Dose Error Reduction System (DERS) software and intuitive workflows to support error prevention. The ES software subsystems are used by Pharmacy Staff, Biomed Staff, IT Staff and Moog Field Service Staff to achieve their specific needs. ES is architected to be scalable, i.e. it can run on a single desktop, many desktops in a campus-based server network, and can be advanced to multiple server-based topology. The applications utilize a common database manager software library along with secure connectivity to the database.

The associated accessories include:

- **Lockbox** capable of mounting to a bar and accepting 500 mL bags and sets
- **Pole clamp** that is tilt adjustable and is capable of mounting both horizontally and vertically to a bar and still allows the pump to be viewed in a vertical orientation

- **PCA Bolus Cable** with 2-meter cable with Micro-B USB Plug
- **USB Data Cable** with 2-meter cable with Micro-B USB Plug at one end and USB Type A plug at the other end
- **Power AC Adapter** cord with input voltage of 100 Vac to 240 Vac and Input line frequency range of 50 Hz to 60 Hz. Rated output voltage of 5.00 Vdc and rated output current of at least 3.0 A
- **Rechargeable Battery** with 2 Lithium-Ion cells in a 1s2p configuration (2 cells in parallel) and rated for at least 23.4 Watt-Hours (3.6 Volts at 6.5 Amp-Hours)
- **Battery Charger** that charges up to 4 battery packs simultaneously

V. INDICATIONS FOR USE

The CURLIN® 8000 ambulatory infusion pump system is indicated for use in home care and clinical settings for the controlled administration of prescribed medical fluids through clinically accepted routes of administration: intravenous, intra-arterial, subcutaneous, epidural, and perineural, to adult patients. The CURLIN® 8000 is not intended for use on pediatric patients. The pump is intended to deliver a variety of therapies (drugs and fluids) which have been approved for these routes of administration. Examples of the therapies, which may be delivered using the CURLIN® 8000 pump, include hydration, parenteral nutrition, anti-infectives, pain management, inotropes, chemotherapy, immune globulin, and biologics. The CURLIN® 8000 is not indicated for the delivery of cellular blood products.

RxManager Enterprise Solution Software allows the user to create and manage pump configurations and therapy-based protocols to be used with the CURLIN® 8000 Ambulatory Infusion Pump.

CURLIN® Administration Sets are intended to be used with CURLIN® infusion pumps to deliver medication from a container to a patient.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CURLIN® 8000 Ambulatory Infusion System and the predicate device are both multi-therapy infusion pumps with dosing software that utilize disposable, sterile administration sets. Both devices infuse a broad range of fluids and medications via a peristaltic pumping mechanism and can operate in continuous, intermittent, variable TPN, or PCA mode. Both devices are indicated for use on adult patients in homecare, infusion suites, oncology and other alternate site locations as appropriate. Both devices provide infusion delivery through accepted clinical routes such as intravenous, intra-arterial, epidural, and subcutaneous

infusions. Both devices operate with similar infusion parameters such as flow rate, flow accuracy, KVO rate, volume limit, and prime mode.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Graphic Color Display
- Microprocessor control
- Internal clock
- Air-in-Line Sensor
- Occlusion Sensor
- History Log
- Programmable Delivery Ranges
- Security Features such as locked access levels and customizable access codes
- Rechargeable Batteries

The following technological differences exist between the subject and predicate devices:

- Volume of air to trigger an Air-in-Line alarm
- Maximum PCA Boluses per Hour
- Programmable Delivery Rate for PCA
- PC Software Compatibility

VII. PERFORMANCE DATA

A safety assurance case, as recommended by the FDA guidance document, Infusion Pumps Total Product Life Cycle, was provided for the subject device. The stated top-level claim of the assurance case is:

> *The Curlin 8000 Ambulatory Infusion System is adequately safe for its intended use.*

The assurance case defines the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments cover the following attributes:

- The top claim is supported by appropriate contextual information.
- Device requirements are adequate, and design is adequately verified and validated.
- Device associated risks are completely identified and adequately mitigated.
- CURLIN® 8000 is adequately reliable to ensure safety over its service life when being used according to its intended use and context of use.

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 device.

Software	Software verification and validation per FDA guidance for the "Content of Premarket Submissions for Device Software Functions" (June 2023) and FDA guidance document "Infusion pump total product life cycle".
Electrical Safety	The electrical safety evaluation of the medical electrical equipment was performed per standards IEC60601-1 medical electrical equipment part1: General requirements for basic safety and essential performance
EMC	EMC evaluation of the medical electrical equipment was performed to: - IEC 60601-1-2 Ed 4.1: Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic disturbances - Requirements and tests Susceptibility testing to 5G, WPT, EAS, NFC & Security Metal Detectors
Device Performance	The essential performance requirements of the device (including feeding sets) 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" including: • Performance testing of essential performance attributes to duration of therapy: Head height Viscosity Back-pressure • Reliability testing • Flow rate accuracy testing across all operating conditions • Alarm detection Battery Air in Line Up and Down Stream Occlusion Hardware and Software failures Pump Unattended

<table>
<tr><td></td><td>Infusion Complete
Alarms comply with IEC 60601-1-8
• Ambulatory
• Transportation
• Environmental Conditions:
Operating Temperature
• Operating Altitude</td></tr>
<tr><td>Human Factors</td><td>Following 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.</td></tr>
<tr><td>Biocompatibility</td><td>The biocompatibility test reports provided were conducted per ISO10993 series of standards following Good Laboratory Practices and the representative product tested passed all acceptance criteria.

CURLIN® 380-series administration sets are classified as external communicating, blood path indirect, prolonged use and the following endpoints have been evaluated:

<table>
<tr><th>Endpoint</th><th>Method</th><th>Standard reference</th><th>Biological Risk Assessment</th></tr>
<tr><td>Cytotoxicity</td><td>Cytotoxicity Study Using the ISO Elution Method</td><td>ISO 10993-5</td><td>Non-cytotoxic</td></tr>
<tr><td>Sensitization</td><td>ISO Guinea Pig Maximization Sensitization Test</td><td>ISO 10993-10</td><td>Non-sensitizer</td></tr>
<tr><td>Irritation or Intracutaneous Reactivity</td><td>ISO Intracutaneous Irritation Study - Extract</td><td>ISO 10993-10</td><td>Non-irritant</td></tr>
<tr><td>Acute systemic toxicity</td><td>ISO Acute Systemic Toxicity Study in Mice</td><td>ISO 10993-11</td><td>Non-toxic</td></tr>
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<tr><td>Material Mediated Pyrogenicity</td><td>USP Rabbit Pyrogen Study, Material Mediated</td><td>USP, General Chapter <151>
ISO 10993-11</td><td>Non-pyrogenic</td></tr>
<tr><td>Subacute/Subchronic toxicity</td><td>ISO Two Week Toxicity Study in the Rat, Repeated Parenteral Administration of Two Extracts</td><td>ISO 10993-11</td><td>Non-Toxic</td></tr>
<tr><td>Hemocompatibility</td><td>ASTM Hemolysis Study - Extract Method</td><td>ASTM F756
ISO 10993-4</td><td>Non-hemolytic</td></tr>
</table>
The CURLIN® 8000 Pump is classified as a surface device, contacting intact skin with prolonged use and the following endpoints have been evaluated:
<table>
<tr><th>Endpoint</th><th>Method</th><th>Standard reference</th><th>Biological Risk Assessment</th></tr>
<tr><td>Cytotoxicity</td><td>Cytotoxicity Study Using the ISO Elution Method</td><td>ISO 10993-5</td><td>Non-cytotoxic</td></tr>
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</table>
</td></tr>
<tr><td>Battery Testing</td><td>The Li-ion battery pack has been tested in accordance with IEC 62133.</td></tr>
</table>

Animal Studies

Animal studies were deemed unnecessary to evaluate the substantial equivalence of the subject device with the predicate device.

Clinical Studies

Human clinical studies were deemed unnecessary to evaluate substantial equivalence of the subject device with the predicate device.

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION SUMMARY

The non-clinical data support the safety of the device, and the hardware and software verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. The test results allowed for a conclusion to be made that the subject device is substantially equivalent to the predicate device.

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
510(k)#	Subject Device	K111275	NA
Manufacturer	Zevex, Inc.	Smiths Medical ASD, Inc.	NA
Indications for Use	The CURLIN® 8000 ambulatory infusion pump system is indicated for use in home care and clinical settings for the controlled administration of prescribed medical fluids through clinically accepted routes of administration: intravenous, intra-arterial, subcutaneous, epidural, and perineural, to adult patients. The CURLIN® 8000 is not intended for use on pediatric patients. The pump is intended to deliver a variety of therapies (drugs and fluids) which have been approved for these routes of administration. Examples of the therapies, which may be delivered using the CURLIN® 8000 pump, include hydration, parenteral nutrition, anti-infectives, pain management, inotropes, chemotherapy, immune globulin, and biologics. The CURLIN® 8000 is not indicated for the delivery of cellular blood products.	The CADD®-Solis VIP Ambulatory Infusion Pump is indicated **for intravenous, intraarterial, subcutaneous, intraperitoneal, perineural, surgical site, epidural space, or subarachnoid space** infusion. PCA (patient-controlled analgesia) delivery is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient controlled analgesia. Continuous delivery allows the infusion of drug/fluid at a constant, programmed rate. Intermittent delivery allows the infusion of a specific volume of drug/fluid at a regular, programmed interval. Step delivery allows an incremental increase in infusion rate to a specified maximum infusion rate for a specified total infusion volume. Taper delivery allows a plateau rate of infusion with the option of tapering at the beginning and/or end and has a programmable KVO rate at the end of the infusion.	Due to the limited use of intraperitoneal and subarachnoid routes of delivery by ambulatory pump users, the two devices are substantially equivalent.
Type of Pump	Multi-therapy Infusion Pump	Multi-therapy Infusion Pump	Same
Pumping Mechanism	Curvilinear Peristaltic	Linear Peristaltic	Specification differences do not impact

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
			substantial equivalence
Patient Population	Adult	Not specified	The subject device is equivalent to the predicate device for the stated patient population that is indicated for use.
Delivery Modes	Continuous, TPN, PCA, Intermittent, Variable	Continuous, PCA, Intermittent, Step (Variable), Taper (TPN)	Same
System delivery accuracy (nominal)	+/- 5% For rates at and above 1mL/hr and bolus doses greater than 2.5mL +/- 15% For rates below 1mL/hr and bolus doses at or less than 2.5mL	+/- 6% 10mL/hr and above and bolus accuracy	Specification differences do not impact substantial equivalence
Time to Occlusion Alarm mL/hr Rate (worst case)	0.1 mL/hr = < 360 min 1.0 mL/hr = < 25 min 25 mL/hr = < 2 min	0.1 mL/hr = ≤ 1200 min 150 mL/hr = ≤ 90 min	Subject device has a tighter specification
Air-in-Line Settings	Settings: • 0.1 mL • 0.5 mL • 1 mL • 2 mL • "Off": still senses air and reports accumulated over 4 mL	Settings: • High Sensitivity (>0.15 mL) • Low sensitivity (>0.4 mL • Off: truly off, does not sense air	Similar
Volume of air to trigger an Air-in-Line alarm	Single bubble reporting is based on the chosen setting: • 0.1 mL • 0.5 mL • 1 mL • 2 mL "Off" senses air and reports accumulated air over 4 mL. Accumulated air is related to the amount of air delivered (per chosen setting) over volume of fluid delivered.	Single bubble reporting is based on the setting chosen: Low: single bubble>400 microliters High: single bubble> 150 microliters Off: does not report any air Accumulated air is related to volume over time. • Accumulated air: greater than 1 mL air over 15 minutes (nominal)	Specification differences do not impact substantial equivalence

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
Ingress Protection	IPX4 - Protection against water splashing	IPX4 – Protection against water splashing	Same
Display	Graphic Color LCD	Color display with 320 x 320 pixels	No impact in equivalence as this change has been validated to be acceptable and equivalent for the intended use
Controls	Microprocessor	Microprocessor	Same
System Components/Features			
Internal clock	Yes	Yes	Same
Air-in-line sensor	Yes	Yes	Same
Occlusion sensor	Up and Down Sensor	Up and Down Sensor	Same
History Log	Yes	Yes	Same
Alarms & Alerts			
Air-In-Line	Audible, LCD message	Audible, LCD message	Same
Air-In-Line Disabled	Audible, LCD message	Audible, LCD message	Same
Low Battery	Audible, LCD message	Audible, LCD message	Same
Empty Battery	Audible, LCD message	Audible, LCD message	Same
Door Open	Audible, LCD message	Audible, LCD message	Same
Down Occlusion	Audible, LCD message	Audible, LCD message	Same
Up Occlusion	Audible, LCD message	Audible, LCD message	Same
Backup Battery	Audible, LCD message	Audible, LCD message	Same
Infusion Complete	Audible, LCD message	Audible, LCD message	Same
KVO Rate Too High	Audible, LCD message	No	Subject device warns while predicate device limits programming from 0-10 mL/hr
Low Bag Volume	Audible, LCD message	Audible, LCD message	Same
Pump Maintenance Due	Audible, LCD message	Audible, LCD message	Same
Release/Remove PCA Cord	Audible, LCD message	Audible, LCD message	Same
Handset Unplugged	Audible, LCD message	Audible, LCD message	Same
Set Not Installed	Audible, LCD message	Audible, LCD message	Same
Unattended Pump	Audible, LCD message	Audible, LCD message	Same
Stuck Key	Audible, LCD message	Audible, LCD message	Same
Malfunction	Audible, LCD message	Audible, LCD message	Same
Invalid Key press	Yes: Audible alert when invalid key is pressed	Yes:	Same

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
		CADD®-Solis provides an optional feature which provides a confirmation sound with a valid keypress.	
Improper flow of fluid alarm/sensor	No	No	Same
Temperature Sensor for the Infusate	No	No	Same
Pump Temperature Sensor	Yes (hot and cold)	Yes (hot)	Specification differences do not impact substantial equivalence
Tone Test	Audible and visual message	Audible	Similar
Security	Unused therapy modes can be blocked out, four access levels, tamper-proof lockbox, customizable access code	Cassette/keypad lock & three customizable security access levels: keypad code; clinician code; administrator code	Similar
Infusion Parameters			
Programmable Delivery Ranges	CONT: 0.1 – 500 mL/h INT: 0.1 – 500 mL/h VAR: 0.1 – 500 mL/h TPN: 10 – 500 mL/h PCA Basic (non-Rx Manager) programming ranges: Basal Rate: 0 or 0.1 - 10 mL/h PCA PSP (Rx Manager) programming ranges Basal Rate: IV: 0 or 0.1 – 100 mL/h SubQ: 0 or 0.1 – 10 mL/h EPI: 0 or 0.1- 35 mL/h PCA Bolus (Basic Program): • Min: 0 when no patient bolus programmed 0.1 for mL • Max: Max PCA Bolus Volume for (Basic) – All Routes: 10 mL PCA Bolus (PSP Program): • Min: 0 (OFF); 0.1 for mL • Max: IV route - 50 mL equiv. EPI route - 25 mL equiv.	CONT: 0.1 – 500 mL/h INT: 0.1-500 mL/hr VAR: 0.4- 500 mL/hr TPN: 0.1-500 mL/hr PCA Basal rate: 0-100 mL/hr PCA (Patient) Dose: 0-50 mL/hr	Within predicate ranges

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
	SubQ route - 10 mL equiv.		
KVO	Yes (all non PCA modes)	Yes (all modes)	Same
KVO Rate	0.1 – 9.9 mL/h	PCA: 0-0.1 mL/h Other modes: 0 – 10 mL/h	Similar
Bag (Reservoir) volume – Programmed value of volume of available fluid in drug container	1 to 9,999 mL	0 to 9,999 mL	Similar
Maximum PCA Bolus Amount	Basic program: 9.9 mL RxM/PSP programming: 50 mL	Maximum 50 mL	Same
Clinician Bolus	Yes	Yes	Same
Maximum Clinician Bolus	Basic Program: 10 mL PSP Program: 50 mL	50 mL	Same
Maximum PCA Boluses per Hour	30 per hour	60 per hour	Specification differences do not impact substantial equivalence
PCA Dose lockout time	2 minutes – 24 hours	1 minute – 24 hours	Similar
Bolus Delivery Limit Methods	1-hour limit OR Max # of Boluses/hour	1-12-hour limit OR Max # of Boluses/hour	Specification differences do not impact substantial equivalence
Programmable Delivery Rate – PCA	Basic infusion 10-125 mL/h PSP 10-400 mL/h	40 - 250 mL/h	Specification differences do not impact substantial equivalence
Priming Methods	Gravity or Pump	Gravity or Pump	Same
Accessories			
Administration Sets	Yes	Yes	Same
AC adapter	Yes	Yes	Same
Remote Dose Cord	Yes	Yes	Same
Reservoir enclosure (Lockbox)	Yes	Yes	Same
Pole Mount Bracket	Yes	yes	Same
Electrical Safety			
Electrical Safety	Compliant with ANSI/AAMI 60601-1:2005/A1:2012	Compliant with IEC 60601-1	Same

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
Electromagnetic compatibility	Compliant with IEC 60601-1-2:2014	Compliant with IEC 60601-1-2	Same
Mechanical and Power Requirements:			
Pump Size	5.5" H x 4.3" W x 2.75" D	5.0" H x 4.0" W x 1.6" D	Similar
Pump Weight	25 oz. with batteries	21 oz. with batteries	Similar
Power Sources	1.5V "C" cell Alkaline (2) Rechargeable battery pack AC Adapter	1.5V "AA" cell Alkaline (4) Rechargeable battery pack AC Adapter	Similar
Alkaline Battery Life	10 Hours @ 500 mL/h 30 Hours @ 125 mL/h 50 Hours @ 2 mL/h	11 Hours @ 500 mL/h 37 Hours @ 125 mL/H 139 Hours @ 1 mL/h	Similar, though calculated at different mL/h
Rechargeable Battery Life	10 Hours @ 500 mL/h 30 Hours @ 125 mL/h 85 Hours @ 2 mL/h	10 Hours @ 500 mL/h 30 Hours @ 125 mL/H 67 Hours @ 1 mL/h	The subject device battery life is longer for infusions run at lower rates
Operating Environment			
Temperature	15°C (59°F) to 40°C (104°F)	15°C (59°F) to 40°C (104°F)	Same
Relative Humidity	15% to 90%	20% to 90%	Similar
Atmospheric Pressure	70 kPa to 106 kPa	70 kPa to 106 kPa	Same
Storage Environment			
Temperature	-20°C (-4°F) to 60°C (140°F)	-20°C (-4°F) to 60°C (140°F)	Same
Relative Humidity	15% to 93%	20% to 90%	Similar
Dose Error Reduction Software			
Device Feature	**CURLIN® Rx Manager**	**CADD®-Solis Medication Safety Software V 3.1**	**Comparison**
510(k)#	Subject Device	K111275	NA
PC Software Compatibility	Windows 10	Windows 2000, XP, VISTA, Windows 7, Administrator only: Windows Server 2003, Server 2008, Server 2008R	Differences in supported Windows Operating Systems do not raise questions of safety and effectiveness
Protocol Programming	Yes	Yes	Same
View Reports	Yes	Yes	Same
Print Reports	Yes	Yes	Same
Save Reports	Yes	Yes	Same
Event Log Viewing	Yes	Yes	Same
Rx (pump History/Settings Viewing)	Yes	Yes	Same

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
Password Protected	Yes	Yes	Same
Units programming	Yes	Yes	Same
Concentration programming	Yes	Yes	Same
Continuous rate programming	Yes	Yes	Same
Demand Dose programming	Yes	Yes	Same
Epidural Mode on/off	Yes	Yes	Same
New Patient feature	Yes	Yes	Same
Program limits (soft and hard limits) programming	Yes	Yes	Same
Pump/Module ID Storage and retrieval	Yes	Yes	Same
Date/Time format	Yes	Yes	Same
Parameters from Drug Library Mismatch	When a user enters a parameter value, RxManager checks that value against preset hard and soft dosing limits. If the value is not within the limits, RxManager warns the user there may be an error.	Therapy based customized protocols with Hard and/or Soft Maximum and Minimum delivery rates Visual alerts when soft limit maximum is exceeded	Same
Administration Sets			
Device Feature	**CURLIN® Administration Sets**	**CADD® Administration Sets**	**Comparison**
510(k)#	Subject Device	K170982	NA
Free-flow Protection	Yes	Yes	Same
Biocompatible	Yes	Yes	Same
Non-DEHP	Yes	Yes	Same
Latex free	Yes	Yes	Same
Prescription Only	Yes	Yes	Same
Non-pyrogenic	Yes	Yes	Same
Sterile	Yes	Yes	Same
Hospital or Home Use	Yes	Yes	Same
Air Eliminating Filter	Yes	Yes	Same
Materials of Construction	Tubing - PVC Bag Spike - ABS Outlet housing – Polycarbonate Inlet housing - Polycarbonate	T Tubing - PVC Bag Spike - ABS Outlet housing – Polycarbonate Inlet housing - Polycarbonate	Same

Device Name	CURLIN® 8000	CADD®-Solis VIP Model 2120	Comparison
Administration Set Functionality			
Free-flow protection	Normally closed (after actuation) spring-biased clamping mechanism. Manually openable for priming.	Flow Stop free flow protection device is part of the CADD® cassette. -Spring based clamping mechanism. -Manually openable for priming.	Similar
Free-flow protection plunger	Pinches tubing when latch is opened to prevent free flow.	Pinches tubing when latch is opened to prevent free flow.	Same

IX. CONCLUSIONS

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Curlin 8000 Ambulatory Infusion System is substantially equivalent to the CADD-Solis VIP Model 2120 Infusion System cleared under K111275 with respect to the indications for use, target populations, treatment method, and technological characteristics.