October 3, 2024

Zevex, Inc.
Santosh Bhagat
Regulatory Affairs Manager
4314 Zevex Park Lane
Salt Lake City, Utah 84123

Re: K242660
Trade/Device Name: Curlin 8000 Ambulatory Infusion System; Enterprise Solution (ES) Software; Curlin 380-series Administration Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: FRN, FPA
Dated: August 28, 2024
Received: September 4, 2024

Dear Santosh Bhagat:

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,

Juliane C. Lessard -S

Juliane C. Lessard, 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

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.*

Submission Number *(if known)*

K242660

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, and to adult and 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.**

# 510(k) Summary

Date: September 03, 2024

## I. SUBMITTER

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

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

**Contact Person:**

Santosh Bhagat
Manager, Regulatory Affairs
Cell Phone: (385) 256-8649

## 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

CURLIN® 8000 Ambulatory Infusion System with Rx Manager Enterprise Solution Software (K232793)

## 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 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

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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 be installed on one to many desktops in a campus-based server network. 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 and 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 technological characteristics are identical to the original device as there were no changes made to the Curlin 8000 Ambulatory Infusion Pump. The only update was to add the pediatric population to the Indication for Use and Intended Use after testing to ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)] was completed.

## VII. PERFORMANCE DATA

There are no technological changes made to the subject device and hence no new performance data was gathered. The only update was to add the pediatric population to the Indication for Use and Intended Use after testing to ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)] was completed.

| Device Change | Risks | Verification/ Validation | Acceptance Criteria | Summary of Results |
|---|---|---|---|---|
| Add pediatric population to indication of use by fulfilling requirements specified in ANSI/AAMI/ISO 10993-7 (2008)+Amd 2019 for EO and ECH residuals | Post sterilization exposure to EO and ECH Residuals | Full EO sterilization Cycle with extended aeration time was conducted for Validation of EO/ECH residuals under simulated use extraction method | Per ANSI/AAMI/ISO 10993-7 (2008) + Amd 2019 for EO and ECH residuals, for neonates (3.5kg body mass per CNC guidelines):<br><br>**EO<= 0.21mg/d**<br><br>*(Tolerable exposure for EO = 0.30 mg/kg/d x 3.5 kg x 0.2) (ANSI/AAMI/ISO 10993-7 (2008)+Amd 2019, Section G.6.3).)*<br><br>**ECH <= 0.19mg/d**<br><br>*(Tolerable exposure for ECH = 0.27 mg/kg/d x 3.5 kg x 0.2) (ANSI/AAMI/ISO 10993-7 (2008)+Amd 2019, Section H.4.1.2).)* | Pass<br><br>*EO = 0.022mg/d ( 48 hrs)*<br><br>*ECH = 0.171mg/d (48 hrs)* |

### 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 technological characteristics are identical to the original device as there were no changes made to the Curlin 8000 Ambulatory Infusion Pump. The only update was to add the pediatric population to the Indication for Use and Intended Use after testing to ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)] was completed.

| | Predicate | Subject |
|---|---|---|
| **Indications for Use**<br><br>**(LS-61765)** | 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.<br><br>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. | 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 and 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,<br><br>chemotherapy, immune globulin, and biologics. The CURLIN 8000 is not indicated for the delivery of cellular blood products.<br><br>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.<br><br>CURLIN Administration Sets are intended to be used with CURLIN infusion pumps to |

| | Predicate | Subject |
|---|---|---|
| | CURLIN Administration Sets are intended to be used with CURLIN infusion pumps to deliver medication from a container to a patient. | deliver medication from a container to a patient. |
| **Intended Use**<br>**(LS-61765)** | The CURLIN 8000 ambulatory infusion system is intended for use on adult patients in Home Care and Clinical settings to provide the infusion of a broad range of fluids and medications. The pump will provide infusion delivery through accepted clinical routes of administration.<br>For Home Care settings this includes:<br>• intravenous • epidural<br>• subcutaneous • perineural<br>For Clinical (non-home care) settings this includes:<br>• intravenous • epidural<br>• intra-arterial • perineural<br>• subcutaneous | The CURLIN 8000 ambulatory infusion system is intended for use on adult and pediatric patients in Home Care and Clinical settings to provide the infusion of a broad range of fluids and medications. The pump will provide infusion delivery through accepted clinical routes of administration.<br>For Home Care settings this includes:<br>• intravenous • epidural<br>• subcutaneous • perineural<br>For Clinical (non-home care) settings this includes:<br>• intravenous • epidural<br>• intra-arterial • perineural<br>• subcutaneous |

## IX. CONCLUSIONS

Full EO sterilization Cycle with extended aeration time was conducted for validation of EO/ECH residuals under simulated use extraction. This testing indicated that the EO/ECH residual levels were below those required by ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009) AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]. The test

results allowed for adding pediatric patients to the Indications for Use and Intended Use statements of the device.