DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2014

Zyno Medical LLC
Mei Zhang
Director of Engineering
177 Pine Street
Natick, MA 01760

Re: K140783
Trade/Device Name: Halo Ambulatory Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, MEA, FPA
Dated: September 19, 2014
Received: September 24, 2014

Dear Ms. Zhang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140783

Device Name
Halo Ambulatory Infusion System

Indications for Use *(Describe)*

The Halo Ambulatory Infusion System is intended to deliver medications and/or fluids to a patient under the direction or supervision of physician or other certified healthcare professional. The device is intended for subcutaneous, perineural, epidural and intravenous infusion. The device is intended for 240 hours or1500mL of infusion, whichever limit is reached first.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY
for the
Halo Ambulatory Infusion System

Submitted By:

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Date Submitted:	September 19th, 2014
Establishment Registration No:	3006575795
Device Proprietary Name:	Halo Ambulatory Infusion System
Device Common, Usual or Classification Name:	Ambulatory Infusion System
Device Class:	Class II
Panel:	80 General Hospital

Product codes: Infusion Pump, product code FRN (21 CFR 880.5725);
PCA Infusion Pump, product code MEA (21 CFR 880.5725); and
Administration Set, product code FPA (21 CFR 880.5440)

Predicate Device: CADD-Legacy PCA Model 6300 (K982839)
ambIT Continuous Ambulatory Infusion Pump (K033325)
CADD-Solis VIP Ambulatory Infusion Pump (K111275)
Zyno Medical Administration Set (K120685)

I. INTENDED USE

The Halo Ambulatory Infusion System is intended to deliver medications and/or fluids to a patient under the direction or supervision of physician or other certified health care professional. The device is intended for subcutaneous, perineural, epidural and intravenous infusion. The device is intended for 240 hours or1500mL of infusion, whichever limit is reached first.

II. DEVICE DESCRIPTION

The Halo Ambulatory Infusion System includes Halo Ambulatory Infusion Pump ("Halo Pump") and Halo Administration Set. The system provides measured drug / fluid therapy for subcutaneous, perineural, epidural and intravenous delivery to patient under the direction or supervision of physician or other certified health care professional. The design philosophy was "Simplicity = Safety". Verification and validation data have demonstrated that this is a simple, safe and reliable infusion device for patient in the clinical and non-clinical environments, including but not limited to hospital, homecare, and outpatient settings.

Halo Ambulatory Infusion Pump

The Halo Ambulatory Infusion Pump ("Halo Pump") has a microprocessor controlled motor that drives a mechanical pumping mechanism to deliver fluid at a controlled rate, same as the CADD-Legacy PCA 6300 Ambulatory Infusion Pump (K982839) and ambIT Continuous Ambulatory Infusion Pump (K033325).

The Halo Pump interfaces with user via keypad, LED and LCD. Infusion parameters can be set up by operating the keypad, and displayed on the LCD. The pump includes sensors for detection of upstream occlusion, downstream occlusion, cassette loading error, and pumping mechanism malfunction. Error conditions can be displayed on LCD, and redundantly indicated by a LED light and audio alert. The electronics is powered by a battery. The materials of construction for Halo Pump components are widely used in the medical industry.

The Halo Pump is intended for therapies that require a continuous infusion with optional Patient Controlled Analgesia (PCA).

Halo Administration Set

The Halo Administration Set is designed to administer fluids / medication from a container to a patient through a needle or a catheter. Major components include spike, cassette, slide clamp, filter, and luer lock. The air-eliminating filter prevents air from entering into a patient.

The Halo Administration Set can be used with Halo Pump or for gravity infusion. It is similar to the predicate device, Zyno Medical Administration Sets(K120685), which can be used with Z-800 Infusion Pump or gravity infusion.

III. SUMMARY OF STUDIES

References:

Zyno Medical performed extensive verification and validation testing on the Halo Pump and Administration Set. Testing was completed in accordance with FDA's Guidance / draft guidance listed below:

A. *Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions,* issued on April 23, 20 10
B. *Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]* issued on July 11, 2008
C. *Draft Guidance for Industry and FDA Administration Staff –Design Considerations for Devices Intended for Home Use,* issued on December 12, 2012
D. *Draft Guidance for Industry and FDA Administration Staff –Applying Human Factors and Usability Engineering to Optimize Medical Device Design* issued on June 22, 2011
E. *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Device.* Issued on: May 11, 2005

Safety and Effectiveness Verification and Validation

A summary of the verification and validation testing performed is provided below:

Testing Performed	Results
Halo Administration Set testing, including Biocompatibility, Pyrogenicity, Physical & Mechanical Testing, Chemical Testing, Sterility Testing, Aging testing, DEHP, Integration Testing with Halo Pump (Per reference B above, ISO / AAMI / ASTM standards)	Pass
Halo Pump software verification and validation testing (Per reference E)	Pass
Halo Ambulatory Infusion System basic safety and essential performance testing: (Per IEC 60601-1 and 60601-2-24)	Pass
Halo Pump Electromagnetic Compatibility Testing (Per IEC 60606-1-2)	Pass
Halo Ambulatory Infusion System Alarm System Testing (Per IEC 60601-1-8)	Pass
Verification and Validation of Halo Ambulatory Infusion System used in the home healthcare environment (Per reference C above and IEC 60601-1-11)	Pass
Additional Testing for Verification of Safety and Effectiveness (Per reference A, design requirements, and hazard analysis)	Pass
Usability Validation Testing of Halo Ambulatory Infusion System (Per reference A, B, C, D, E above; IEC 6060-1-6; IEC 62366)	Pass

Testing Conclusion

All testing met pre-established specifications, and successfully demonstrated that the Halo Ambulatory Infusion System performed as intended. The testing results allowed for a conclusion to be made that the Halo Ambulatory Infusion System, which includes Halo Ambulatory Pump, Halo Administration Set, and accessories is as safe and effective as the predicate devices.

Clinical Studies

Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the Halo Ambulatory Infusion System.

VI. STATEMENT OF EQUIVALENCE

The Halo Ambulatory Pump and Halo Administration Set are substantially equivalent to the predicate devices, based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the devices for their intended uses. The test results did not raise any safety or performance questions, and confirmed that the Halo Ambulatory Pump and Halo Administration Set are substantially equivalent to the predicate devices.

Table 1: Equivalency Matrix of Halo Ambulatory Infusion Pump and Predicate Devices

Parameter	Halo Ambulatory Infusion Pump	CADD-Legacy PCA 6300 Model (K982839)	ambIT Continuous Infusion Pump (K033325)	CADD –Solis VIP Ambulatory Infusion Pump (K111275)
Pump Type	Ambulatory Infusion Pump	Ambulatory Infusion Pump	Ambulatory Infusion Pump	Ambulatory Infusion Pump
Intended use	The Halo Ambulatory Infusion System is intended to deliver medications and/or fluids to a patient under the direction or supervision of physician or other certified healthcare professional. The device is intended for subcutaneous, perineural, epidural and intravenous infusion. The device is intended for 240 hours or1500mL of infusion, whichever limit is reached first.	The CADD-Legacy pump is suitable for intravenous, intra-arterial, subcutaneous, intraperitonal, epidural space, or subarachnoid space infusion.	The ambIT Infusion Pump is intended for continuous volumetric delivery of intravenous medicines and /or fluids into patient at a consistent volume for prescriptive treatment by a physician.	The CADD –Solis VIP Ambulatory Infusion Pump is indicated for intravenous, intra-arterial, 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
Infusion Mode	Continuous Mode Bolus Mode (PCA)	Continuous Mode with Bolus (PCA)	Continuous Mode	PCA, Continuous, Intermittent, Step, Taper

Parameter	Halo Ambulatory Infusion Pump	CADD-Legacy PCA 6300 Model (K982839)	ambIT Continuous Infusion Pump (K033325)	CADD –Solis VIP Ambulatory Infusion Pump (K111275)
Fundamental Technology	Mechanical pumping mechanism driven by a motor which is controlled by a microprocessor	Mechanical pumping mechanism driven by a motor which is controlled by a microprocessor	Mechanical pumping mechanism driven by a motor which is controlled by a microprocessor	Mechanical pumping mechanism driven by a motor which is controlled by a microprocessor
Volumetric Accuracy	+-5%	+-6%	+-6%	+-6%
Display	LCD, LED	LCD, LED	LCD, LED	LCD, LED
Operating Temperature	+5°C to +40°C (+41°F to +104°F)	+2°C to+ 40°C (+35°F to +104°F)	+10°C to +43°C (+50°F to +110°F)	+15°C to +40°C (+59°F to +104°F)
Alarms / Alert / Status Display	•Run Indicator Light & Icon on LCD • Pause Indicator • Upstream Occlusion • Downstream Occlusion • Battery Empty • Pump End of Life • Cassette Loading error • Pumping System Error • Firmware Error • Infusion Completed • Pump Unattended • Incorrect Programming • Bolus Blocked • Keypad Locked / Unlocked	• Battery Low • Battery Depleted • Battery Dislodged • Pump Stopped • Pump Fault • Low Reservoir Volume • High Delivery Pressure • Air-In-Line • Disposable not attached when run attempted • Service due • Motor Locked • Upstream Occlusion • Reservoir Volume Empty • Program incomplete • Remote Dose Cord Removed • Key Stuck • Disposable Detached	• Run Indicator Light • Pause Indicator • Downstream Occlusion • Cassette not Mounted on Pump • Low Battery • Dead Battery • Malfunction • Infusion Complete	• Battery Low • Battery Depleted • Battery Removed • Battery Unusable • Pump Stopped • Pump Fault • Pressure Sensor Faulty • Air-In-Line • Upstream Occlusion • Reservoir Volume Empty • Program incomplete • Remote Dose Cord Key Stuck • Key Stuck • Disposable type invalid • Disposable not latched • Disposable Detached • AC adaptor disconnected • Preventive Maintenance Due
Use Environment	Clinical and non-clinical	Clinical and non-clinical	Clinical and non-clinical	Clinical and non-clinical

Parameter	Halo Ambulatory Infusion Pump	CADD-Legacy PCA 6300 Model (K982839)	ambIT Continuous Infusion Pump (K033325)	CADD –Solis VIP Ambulatory Infusion Pump (K111275)
Size	4.2 in. x 2.3 in. x 1.6 in. (108mm x 58mm x 40 mm)	4.4 in. x 3.8 in. x 1.6 in. (112mm x 96 mm x 40mm)	6.875 in. x 2.16 in. x 1.4 in. (175 mm x 55 mm x 36 mm)	5 in x 4 in x1.6 in (127 mm x 102 mm x 41 mm)
Weight	6.1 ounces (173 grams)	13.8 ounces (391 grams)	6.4 ounces (181.4 grams)	21 ounces (595 gramps)

Table 2: Equivalency Matrix of Halo Administration Set and the Predicate Device

Parameter	Halo Administration Set	Zyno Medical Administration Set (K120685)
Device Type	Administration Set	Administration Set
Intended use	To administer fluids from a container to a patient through a needle or a catheter	To administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein
Tubing material	Standard PVC	Standard PVC
Single use?	Yes	Yes
Sterile?	Yes	Yes
Sterilization method	EtO	EtO
Set based Free Flow Protection	Yes	Yes
Components	Spike, tubing, cassette, slide clamp, filter, Luer Lock	Spike, drip chamber, tubing, roller clamp, slide clamp, pinch clamp, filter, Y-site, Luer Lock
ISO 8536 compliant?	Yes	Yes
ISO 10993 compliant?	Yes	Yes