DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 30, 2016

Zyno Medical LLC
Mei Zhang, PhD
VP Of Engineering
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Re: K153193
Trade/Device Name: Halo II Ambulatory Infusion System (also with trade names Nimbus II Ambulatory Infusion System; EVAA Ambulatory Infusion System)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, MEA, FPA
Dated: July 11, 2016
Received: July 12, 2016

Dear Mei 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" (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 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153193

Device Name
Halo II Ambulatory Infusion System (Also with trade names Nimbus II Ambulatory Infusion System; EVAA Ambulatory Infusion System)

Indications for Use *(Describe)*

The Halo II 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 in clinical or nonclinical environments, such as homes. The device is intended for subcutaneous, percutaneous, perineural, epidural and intravenous infusion, including but not limited to patient controlled analgesia (PCA) delivery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) - K153193 - SUMMARY

Submitted By:

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Date Submitted: August 29th, 2016
Establishment Registration No: 3006575795

Device Proprietary Name: Halo II Ambulatory Infusion System
(also with trade names:
Nimbus II Ambulatory Infusion System;
EVAA Ambulatory Infusion System)

Device Common, Usual or Classification Name: Infusion Pump
Classification Regulation: 21CFR880.5725
Device Class: Class II
Panel: 80 General Hospital

Product codes: FRN, MEA, FPA

Predicate Device: Halo Ambulatory Infusion System (K140783)
CADD-Solis VIP Ambulatory Infusion Pump (K111275)
Zyno Medical Administration Set (K120685)

I. INDICATIONS FOR USE

The Halo II 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, percutaneous, perineural, epidural and intravenous infusion, including but not limited to patient controlled analgesia (PCA) delivery.

II. DEVICE DESCRIPTION

Halo II Ambulatory Infusion System also will be marketed under the trade name "Nimbus II Ambulatory Infusion System" and "EVAA Ambulatory Infusion System"; there are no differences in these devices.

The Halo II Ambulatory Infusion System includes an ambulatory infusion pump and administration set. It is used to deliver medications and/or fluids to a patient under the direction or supervision of physician or other certified healthcare professional. This is a device modified from its predicate device Halo Ambulatory Infusion System (K140783). Modifications include allowing users to change battery therefore enabling pump use beyond 240 hours / 1500mL. The original motor was replaced with a longer life one to support extended pump life. Software was updated accordingly to realize the changes. The administration set remains exactly the same.

Halo II Ambulatory Infusion Pump

The Halo II Ambulatory Infusion Pump has a microprocessor controlled motor that drives a peristaltic pumping mechanism to deliver fluid at a controlled rate, same as the Halo ambulatory infusion pump (K140783) and CADD-Solis VIP ambulatory infusion pump (K111275).

The 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 the Halo II pump components are widely used in the medical industry.

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

Halo II Administration Set

The Halo II Administration Set is exactly the same as Halo Administration Set (K140783). It 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 administration set can be used with Halo II 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 ambulatory pump and administration Set. Testing was completed in accordance with FDA's Guidance / draft guidance listed below:

A. *Guidance for Industry and FDA Staff: Infusion Pumps Total Product Life Cycle,* issued on December 2, 2014
B. *Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]* issued on July 11, 2008
C. *Guidance for Industry and FDA Staff: Design Considerations for Devices Intended for Home Use,* issued on November 24, 2014
D. *Guidance for Industry and FDA Administration Staff –Applying Human Factors and Usability Engineering to Medical Devices* issued on February 3, 2016
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

Performance Testing Summary:

The following performance data was the basis for the substantial equivalence determination:

An assurance case was provided for the Halo II Ambulatory Infusion System, per the FDA guidance document for infusion pumps (Reference A listed above).

The stated goal of the assurance case is to document that the design of the Halo II Ambulatory Infusion System is adequately safe for its intended use.

The assurance case defined the device system, including the indications for use, system specifications, use environments, and user population. The supporting assurance arguments covered the following attributes:

- **All potential risks have been mitigated and residual risk is acceptable.** Potential 14 types of harms resulting from 8 hazards and hazardous conditions have been extensively studied and analyzed. All potential risks have been adequately mitigated.

- **Design verification and validation of device specifications are adequate**. Device description is presented in the Assurance Case Report, including design input requirements, design output, product specifications, and comparison with predicate devices. A traceability matrix is provided to establish a connection between design input and design output through verification and validation activities which have been completed to demonstrate adequate implementation of the respective design requirements.

o Device reliability is adequate. Product reliability has been properly specified, verified, validated, and ensured through design and manufacturing process.

The following specific evidence was included within the assurance case:

Functionality
• Testing to characterize the system functionality over expected conditions of use
• Flow rate characterization and flow rate accuracy
• Alarms testing,
• Integrity of fluid pathway components
• Reliability assessment

Software
• Device Software Version 1.0.1 was developed in accordance with EN 62304:2006 and evaluated as part of this 510(k) Submission
• Documentation for Major Level of Concern software was provided, as recommended by the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Reference E listed above)
• Software verification and validation testing, including software static analysis
• Zero unresolved software anomalies were reported

Electrical Safety and Electromagnetic Compatibility
• Electrical safety and electromagnetic compatibility were verified through testing in accordance with UL60601-1, IEC 60601-2-24 and IEC 60601-1-2
•Ambulatory Infusion System Alarm System Testing Per IEC 60601-1-8

Biocompatibility
•Biocompatibility tested per ISO 10993-1:
- o Cytotoxicity per ISO 10993-5
- o Sensitization per ISO 10993-10
- o Hemolysis per ISO 10993-4
- o Irritation per ISO 10993-10
- o Acute Systemic Toxicity per ISO 10993-11
- o Subchronic Systemic Toxicity per ISO 10993-11

Sterility and Shelf Life
• The administration set is sterilized with Ethylene Oxide gas.
• Sterilization validation methodology in accordance with ISO 11135 was described.
• Ethylene oxide residuals for ethylene oxide and ethylene chlorohydrin specification limits were established per ISO 10993-7.
• Sterility Assurance Level is 10^{-6}
• Non-pyrogenic claims for the administration set were verified through Kinetic Chromogenic LAL per ANSI/AAMI ST72 and Rabbit pyrogen test per United States Pharmacopeia <151>.

• A Shelf Life of 3 years was established with accelerated aging data per ASTM F1980-07. Testing verified package integrity and functional attributes of the administration set remained within established specifications.

Home use environment
Verification and Validation of Halo II Ambulatory Infusion System used in the home healthcare environment per IEC 60601-1-11, and FDA guidance on Design Considerations for Devices Intended for Home Use (Reference C listed above).

Human Factors and Usability
• Simulated use/human factors studies – A Clinical Evaluation was determined not to be required for the Halo II Ambulatory Infusion System. A simulated use study of human factors was conducted with intended users in the intended use environment that evaluated device performance, possible use error and user perception of difficulties with pump use. The study assessed the critical tasks or use scenarios where use related errors are most likely to occur. The study was performed with reference to FDA guidance (Reference D listed above).
• Usability Validation Testing of Halo II Ambulatory Infusion System (IEC 6060-1-6; IEC 62366)

The assurance case and referenced evidence demonstrate that the Halo II Ambulatory Infusion System functions as designed and can be operated by the user as intended through the user interface and instructions provided.

Study Conclusion
All testing met pre-established specifications, and demonstrated that the Halo Ambulatory Infusion System performed as intended. The testing results allowed for a conclusion to be made that the Halo II Ambulatory Infusion System, which includes ambulatory pump, administration set, and accessories, is substantially equivalent to the named predicates.

IV. 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 confirmed that the Halo II Ambulatory Pump and Administration Set are substantially equivalent to the predicate devices.

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

Parameter	Halo II Ambulatory Infusion Pump	Halo Ambulatory Infusion Pump (K140783)	CADD –Solis VIP Ambulatory Infusion Pump (K111275)
Pump Type	Ambulatory Infusion Pump	Ambulatory Infusion Pump	Ambulatory Infusion Pump
Indications for use*	The Halo II 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, percutaneous, perineural, epidural and intravenous infusion, including but not limited to patient controlled analgesia (PCA) delivery.	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 –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

Parameter	Halo II Ambulatory Infusion Pump	Halo Ambulatory Infusion Pump (K140783)	CADD –Solis VIP Ambulatory Infusion Pump (K111275)
Infusion Mode	Continuous Mode Bolus Mode (PCA)	Continuous Mode Bolus Mode (PCA)	PCA, Continuous, Intermittent, Step, Taper
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
Volumetric Accuracy	+-5%	+-5%	+-6%
Display	LCD, LED	LCD, LED	LCD, LED
Operating Temperature	+5°C to +40°C (+41°F to +104°F)	+5°C to +40°C (+41°F to +104°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 Service Due • Cassette Loading error • Pumping System Error • Firmware Error • Infusion Completed • Pump Unattended • Incorrect Programming • Bolus Blocked • Keypad Locked / Unlocked	•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 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
Size	4.2 in. x 2.3 in. x 1.6 in. (108mm x 58mm x 40 mm)	4.2 in. x 2.3 in. x 1.6 in. (108mm x 58mm x 40 mm)	5 in x 4 in x1.6 in (127 mm x 102 mm x 41 mm)
Weight	6.1 ounces (173 grams)	6.1 ounces (173 grams)	21 ounces (595 gramps)

*Although there are differences in the wording of indications for use statements, the differences are not critical to the intended use of the device. The devices are all intended to deliver medications / fluids to a patient. The new indications for use does not include a time limit of the device, this does not change the intended use or raise new questions of safety and effectiveness, because the device service life is still monitored by an internal odometer, the same way as the predicate device. The extended use is verified through testing under normal use conditions, as

well as under extreme conditions, such as continuously operated under specified lowest and highest temperature. The reliability has been assessed as adequate based on testing results and analysis.

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

Parameter	Halo II Administration Set	Halo Administration Set (K140783)	Zyno Medical Administration Set (K120685)
Device Type	Administration Set	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 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	Standard PVC
Single use?	Yes	Yes	Yes
Sterile?	Yes	Yes	Yes
Sterilization method	EtO	EtO	EtO
Set based Free Flow Protection	Yes	Yes	Yes
Components	Spike, tubing, cassette, slide clamp, filter, Luer Lock	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	Yes
ISO 10993 compliant?	Yes	Yes	Yes