MOOG

K131154

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Moog Medical Devices Group
4314 Zevex Park Lane
Salt Lake City, Utah 84123

ph 801.264.1001
fx 801.264.1051
800.970.2337

www.moog.com/medical

CURLIN INFUSION

ZEVEX ENTERAL

510(k) Summary

This summary of the "Special 510(k): Device modification" information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Date prepared: 11/21/2013

Owner's name & address: ZEVEX, Inc.
4314 Zevex Park Lane
Salt Lake City, UT 84123

Phone number: 801-264-1001 x291

Fax number: 801-264-1051

Contact person: Niloufar (Nellie) Samimi

Trade name: EnteraLite® Infinity® Enteral Feeding Pump

Common name: Disposable Tubing sets

Classification name: 21 CFR 880.5725 Infusion pump

Substantial equivalence claimed to:
K031199- EnteraLite Infinity Enteral Feeding Pump- ZEVEX, INC

Description:
The EnteraLite® Infinity® Enteral Feeding Pump as referred to as Infinity® with disposable set is a small, lightweight pump used to dispense liquid nutrients at a user controlled rate to patients. The device may be used in the hospital or at home by bedridden or ambulatory patients. The device is also designed for use with pediatric patients.

The device is software controlled, variable flow rate, peristaltic pump. It operates up to 24 hours (at a nominal flow rate of 125 ml/hr) from internal rechargeable batteries. The batteries are recharged by a wall mounted charger that plugs into a standard 100 to 240 volt alternating current wall socket. The charger is available in various input voltage and plug configurations to accommodate international requirements. The charger converts line voltage to a safe low voltage of 5 volts DC that is supplied from the charger to the pump. A "fuel gauge" type indicator on the pump's LCD display continuously shows the state of battery charge.

The pump motor runs at a single speed and is turned on and off at programmed intervals to obtain the desired flow rate. The motor drive circuit is controlled by a microcontroller that allows the motor to pause longer at lower flow rates with correspondingly shorter

pauses at higher flow rates. The software embodied within the microcontroller is validated and verified as part of the design process.

The pump includes several safety features. An air-in-line sensor rapidly detects whenever nutrient flow is interrupted and alerts the user with both a visual and audible alarm. Two pressure sensors detect occlusions both on the nutrient bag (distal) side and the patient (proximal) side of the pump. The user is alerted to proximal or distal occlusions by both visual and audible alarms.

The disposable tubing set consists of a bag, or spike for nutrient bag, PVC connecting tubing, an integral cassette with a silicone pumping segment, and an enteral adapter. The set also contains a patented anti-free flow device within the cassette, which prevents free flow of fluids if the tubing set is inadvertently or purposely removed from the pump.

A backpack (convertible to a waistpack) is available for use under ambulatory conditions. The pump may be operated in any orientation.

Intended use:
The EnteraLite® Infinity® Enteral Feeding Pump is a rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.

Summary of technological characteristics:
The modified device and the predicate device, have the exact same design features with one exception. The proposed device's cassette component has 3 bumps added creating a greater interference between the cassette and the pump door.

Risk Analysis:
The risk analysis methods used to assess the safety and effectiveness impact of the modification was Failure Modes, Effects and Criticality Analysis (FMECA). The Design Requirements document and Design Verification document was also reviewed.

It was determined that the addition of the bumps to the cassette did not add any new safety risk to the disposable tubing set.

It was determined that he previously conducted design verification activities were still applicable. The proposed design modification will not affect the following:

1. Operation and performance of the cassette.
2. Shelf Life
3. Biocompatibility
4. Packaging and transportation

Non-Clinical Performance Data:
The following verification test reports were performed to verify contact of the door/ top housing to the cassette when installed. Based on the results of this testing including statistical and graphical analysis, the addition of bumps to the cassette passes the acceptance criteria.

Characteristic	Test report	Result summary
Design verification	TR-49430	Pass
Design verification	TR-49071	Pass

Conclusion:
The proposed disposable tubing set is substantially equivalent to the predicate device, disposable tubing set.

The devices have the SAME:

1. Intended use
2. Operating Principle
3. Materials
4. Construction
5. Shelf life
6. Packaging

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

February 12, 2014

ZEVEX, Incorporated
Mr. Niloufar Sammi
Regulatory Affairs Specialist III
4314 Zevex Park Lane
Salt Lake City, Utah 84123

Re: K131154
Trade/Device Name: EnteraLite® Infinity® Enteral Feeding Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZH
Dated: February 5, 2014
Received: February 5, 2014

Dear Mr. Sammi:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer for

Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131154

Device Name
EnteraLite Infinity Enteral Feeding Pump

Indications for Use *(Describe)*
The EnteraLite Infinity Enteral Feeding Pump is a rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.

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)*

Digitally signed by Richard C. Chapman
Date: 2014.02.10 16:01:24 -05'00'

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