October 23, 2023

Vesco Medical, LLC
Chris O'Keefe
VP of Product Development and Innovation
60 Collegeview Road, Suite 144
Westerville, Ohio 43081

Re: K232205
Trade/Device Name: Vesco Q™ Enteral Feeding Pump; Vesco Q™ 500mL Bag Feed Set; Vesco Q™ 1000mL Bag Feed Set; Vesco Q™ 40mm Screw Cap Feed Set; Vesco Q™ ENPlus Feed Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LZH
Dated: July 20, 2023
Received: July 25, 2023

Dear Chris O'Keefe:

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

Digitally signed by Jake K. Lindstrom -S
Date: 2023.10.23 16:07:35 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Vesco Q™ Enteral Feeding Pump System

Indications for Use *(Describe)*
The Vesco Q™ Enteral Feeding Pump System is intended to be used by healthcare professionals, patients and caregivers for the intermittent and continuous delivery of enteral fluids for adult and pediatric (infant, child, and adolescent) feeding therapy in hospital and home care environments.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. Submitter

Official Contact

Name: Chris O'Keefe
Title: VP of Product Development and Innovation
Email: cokeefe@vescomedical.com

Vesco Medical LLC
Address: 60 Collegeview Road, Suite 144
Westerville, OH 43081

Phone: 614-914-5991
Fax: 614-902-3275

Date of Preparation October 23, 2023

II. Device

Trade Name:	Vesco Q™ Enteral Feeding Pump System
Common Name:	Infusion Pump, Enteral, External
Classification Name & Number:	Enteral Infusion Pump 21 CFR 880.5725 Class II Product Code: LZH

III. Legally Marketed Predicate Devices

- EnteraLite Infinity™ Enteral Feeding Pump were cleared under notification K031199 (510k application by ZEVEX, Inc.)
  - Product name: EnteraLite Infinity™ Enteral Feeding Pump
  - 510(k) Number: K031199
  - Manufacturer: Zevex, Inc.
  - Product Code: LZH
  - Device Class: Class II

IV. Device Description

The Vesco Q™ Enteral Feeding Pump System is comprised of an enteral infusion pump and disposable enteral feed sets. The Vesco Q™ Pump is a rotary peristaltic pump engineered to deliver doses of enteral fluids at selectable rates programmed with a newly designed purpose- specific touchscreen interface. The pump body is designed to be ergonomic and portable. The Vesco Q™ Feed Sets are non-sterile, single patient use enteral feed sets that are designed to be anti-free flow until the pump is running. The feed sets are designed with cassettes for the simple loading and unloading of the feed set without a pump door. The feed sets incorporate a female ENFit connector which is compatible with devices that have male ENFit connectors. The ENFit connectors are being implemented within enteral feeding devices to eliminate misconnection with non-enteral feeding devices.

Vesco Q™ Feed Sets are available in three different feed set styles: Bag Feed Sets, ENPlus Feed Sets and Screw Cap Feed Sets. All of the feed sets are made of flexible PVC tubing, a silicone tube, a feed set to pump interface, and a plastic ENFit female connecting port. Bag Feed Sets are available in two different volumes, 500mL and 1000mL. The difference between each feed set is how the liquid nutrition is introduced to the set. The Bag Feed Set has a translucent flexible polymeric film bag, the Safety Screw Spike Feed Set has a plastic spike connector, and the Screw Cap Feed Set has a plastic 40mm threaded opening to connect to feed containers.

The connectors on the proximal end of the extension sets are ENFit ISO 80369-3 compliant. The ENFit connector allows for connections of enteral specific applications while reducing the likelihood of misconnections to non-enteral devices.

The Vesco Q™ Enteral Feeding Pump System is substantially equivalent to the predicate device.

V. Intended Use

The Vesco Q™ Enteral Feeding Pump System is intended to be used by healthcare professional, patients and caregivers for the intermittent and continuous delivery of enteral fluids for adult and pediatric (infant, child, and adolescent) feeding therapy in hospital and home care environments.

VI. Substantial Equivalence Discussion

The Vesco Q™ Enteral Feeding Pump System is substantially equivalent for its intended use, use conditions and use environment compared to the currently marketed predicate EnteraLite® Infinity∞®Enteral Feeding Pump. Tables 6.1 and 6.2 are comparison summaries of the proposed feed sets with the predicate pump sets. Table 6.3 lists the comparison of the proposed pump to the predicate pump regarding substantial equivalence.

Table 6.1 Comparison Summary between the Vesco Q™ Feed Sets and the Predicate Device Pump Sets

Proposed Device Model Number	Device Description	Predicate Device Model Number	Differences
VED-050	500mL Feed Set with ENFit with Transition Connector	INF0500-A	Both devices use the same material and are supported by biocompatibility testing
VED-051	1000mL Feed Set with ENFit with Transition Connector	INF1200-A	Both devices use the same material and are supported by biocompatibility testing
VED-052	40mm Screw Cap Feed Set with ENFit	INF0020-A	Both devices use the same material and are supported by biocompatibility testing
VED-053	ENPlus Feed Set with ENFit	INF0020-A	Both devices use the same material and are supported by biocompatibility testing

Table 6.2 Technical Characteristic Comparison between the Vesco Q™ Feed Sets and the Predicate Device Pump Sets

Proposed Device Number & Device Description	Proposed Device Components	Predicate Device Number & Device Description	Predicate Device Components	Difference in Design	Difference in Material
VED-050 500mL Feed Set with ENFit with Transition Connector	• 500mL Polymeric Film Bag • PVC Tubing • ABS Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Anti-free flow design	INF0500-A 500mL Pump Administration Set with Top Fill Bag	• 500mL Polymeric Film Bag • PVC Tubing • Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Barbed Enteral adaptor • Anti-free flow design	None - Devices are identical in function	None - Devices are of the same materials
VED-051 1000mL Feed Set with ENFit with Transition Connector	• 1000mL Polymeric Film Bag • PVC Tubing • ABS Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Anti-free flow design	INF1200-A 1200mL Pump Administration Set with Top Fill Bag	• 1200mL Polymeric Film Bag • PVC Tubing • Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Barbed Enteral adaptor • Anti-free flow design	None - Devices are identical in function	None - Devices are of the same materials
VED-052 40mm Screw Cap Feed Set with ENFit	• Plastic 40mm Threaded Opening • PVC Tubing • ABS Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Anti-free flow design	INF0020-A Enteral Pump Delivery Set with SpikeRight	• Plastic Spike Connector • PVC Tubing • Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Barbed Enteral adaptor • Anti-free flow design	Moog doesn't have a screw cap enteral feeding set. However, devices are similar in function	Moog doesn't have a screw cap enteral feeding set. However, devices are of the same materials
VED-053 ENPlus Feed Set with ENFit	• Plastic Spike Connector • PVC Tubing • ABS Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Anti-free flow design	INF0020-A Enteral Pump Delivery Set with SpikeRight	• Plastic Spike Connector • PVC Tubing • Plastic Cassette with a silicone tube • Plastic Female ENFit Connector • Barbed Enteral adaptor • Anti-free flow design	None - Devices are identical in function	None - Devices are of the same materials

Table 6.3 Comparison of EnteraLite Infinity™ Enteral Feeding Pump to the Predicate Device Regarding Substantial Equivalence (SE)

Design Features/ Function	EnteraLite Infinity™ Enteral Feeding Pump K031199 (Predicate)	Vesco Q™ Enteral Feeding Pump (Proposed)	Substantial Equivalence
Device Description	Enteral infusion pump and disposable enteral feeding set	Enteral infusion pump and disposable enteral feeding set	Same
Indications for Use	EnteraLite Infinity™ Enteral Feeding Pump is rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.	Vesco Q™ Enteral Feeding Pump is a rotary peristaltic pump engineered to deliver programed doses of enteral fluids at selectable rates.	Same
Environment of Use	Hospital or home	Hospital or home	Same
Patient Population	Patients 1 year and up	Adult and Pediatric (infant, child, and adolescent).	Different
Service life	Unknown	3 years	Different
Design (Pump)	Rotary Peristaltic pump with a motor that runs at a single speed and is turned on and off at programed intervals to obtain the desire flow rate. The motor circuit drive is controlled by a microcontroller with software embedded within the microcontroller.	Rotary Peristaltic pump with a motor that runs at a single speed and is turned on and off at programed intervals to obtain the desire flow rate. The motor circuit drive is controlled by a microcontroller with software embedded within the microcontroller.	Same
Rechargeable Battery	Operates up to 24 hours (at a nominal flow rate of 125mL/hr) from internal rechargeable batteries. Batteries are recharged by a wall mounted charger.	Operates up to 24 hours (at a nominal flow rate of 125mL/hr) from internal rechargeable batteries. Batteries are recharged by a wall mounted charger.	Same
Graphic Display	Backlit LCD	Touchscreen	Different
Safety Features	Air-in-line sensor with visual and audible alarms Occlusion Sensors with visual and audible alarms	Air-in-line sensor with visual and audible alarms Occlusion Sensors with visual and audible alarms	Different design
Design (Feed Sets)	Bag Feed Set & Spike Feed Set: • Polymeric Film Bag (500mL or 1200mL) • DEHP free PVC connecting tubing • Cassette with a silicone tube • Plastic Female ENFit Connector	Bag Feed Sets • Polymeric Film Bag (500mL or 1000mL) • PVC Tubing from bag to cassette • ABS Plastic Cassette with Anti-Free flow Silicone Design	Different

	• Enteral adaptor • Anti-free flow design	• PVC Tubing from cassette to patient enteral connector. • Plastic Female ENFit Connector ENPlus Feed Sets • Plastic Spike Connector • PVC Tubing from cassette • ABS Plastic Cassette with Anti-Free flow Silicone Design • PVC Tubing from cassette to patient enteral connector. • Plastic Female ENFit Connector Screw Cap Feed Sets • Plastic 40mm threaded opening • PVC Tubing from cassette • ABS Plastic Cassette with Anti-Free flow Silicone Design • PVC Tubing from cassette to patient enteral connector. • Plastic Female ENFit Connector	
Single Patient Use	Yes	Yes	Same
Sterility Condition	Non-Sterile Feed Sets	Non-Sterile Feed Sets	Same
Type of Placement	Used with enteral feeding devices with ENFit compliant connector	Used with enteral feeding devices with ENFit compliant connector	Same
ENFit Connector	Yes	Yes; compliant with ISO 80369-3	Same
Anti-free flow	Yes	Yes	Same

VII. Discussion of Differences

There are no differences between the indications for use, use conditions, and use environment of the predicate device and the Vesco Q™ Enteral Feeding Pump System. The primary difference between the predicate and proposed device is the newly designed purpose-specific touchscreen interface and an additional option for feed sets. The touchscreen user interface was designed to be easy to read and intuitive to help mitigate user related hazards. The differences were supported by performance testing.

VIII. Performance Testing

Non-Clinical Tests

Verification and validation testing were performed with the Vesco Q™ Enteral Feeding Pump and the Vesco Q™ Feed Sets. It was found that the pump and feed sets are in compliance with all design and performance requirements based on the completed testing below.

1. Biocompatibility:
    a. Neutral Red Uptake (Cytotoxicity) per ISO 10993-5:2009 & ISO 10993-12:2012
    b. Rabbit Pyrogen per ISO 10993-11:2017, ISO 10993-12:2012 & USP 42-NF37:2019 <151> Pyrogen Test
    c. Intracutaneous Injection per ISO 10993-10:2010 & ISO 10993-12:2012
    d. Systemic Injection per ISO 10993-11:2017 & ISO 10993-12:2012
    e. Kligman Maximization per ISO 10993-10:2010 & ISO 10993-12:2012
2. Safety Assurance Case:
    a. As recommended by the FDA Guidance Document, Infusion Pump Total Product Life Cycle, a safety assurance case was created for the Vesco Q™ Enteral Feeding Pump. The stated top-level claim of the assurance case is supported by the following performance tests.
3. Performance:
    a. Wipe and soak test for pump housing material selection in accordance with Vesco Medical's design requirement
    b. Pumping accuracy test in accordance with Vesco Medical's design requirement
    c. Gear box life cycle test in accordance with Vesco Medical's design requirement
    d. Freefall test in accordance with Vesco Medical's design requirement
    e. Air-in-Line test in accordance with Vesco Medical's design requirement
    f. Button life cycle test in accordance with Vesco Medical's design requirement
    g. Power adapter life cycle test in accordance with Vesco Medical's design requirement
    h. Battery run time test in accordance with Vesco Medical's design requirement
    i. Noise level test in accordance with Vesco Medical's design requirement
    j. Pole clamp weight test in accordance with Vesco Medical's design requirement

k. Occlusion test in accordance with Vesco Medical's design requirement
l. Battery charge time test in accordance with Vesco Medical's design requirement
m. Tensile test on unaged and aged product in accordance with EN ISO 20695:2020
n. Pressure leak test on unaged and aged product in accordance with EN ISO 20695:2020
o. Kink test in accordance with EN 13868:2002
p. Anti-free flow test on unaged and aged product in accordance with Vesco Medical's design requirement
q. Free flow rate test on unaged and aged product in accordance with Vesco Medical's design requirement
r. Bolus accuracy in accordance with Vesco Medical's design requirement
s. Bolus accuracy under various conditions in accordance with Vesco Medical's design requirement
t. Cleanability and performance in accordance with Vesco Medical's design requirement

4. Human Factors and Usability Validation Test in accordance with Vesco Medical's design requirement
5. Electromagnetic Compatibility Validation in accordance with IEC 60601-1-2
6. Hardware, Software, and Mechanical Safety Validation in accordance with IEC 60601-1
7. Software Verification and Validation test as recommended by the FDA guidance document Infusion Pump Total Product Life Cycle
8. Risk Hazard Analysis in accordance with ISO 14971:2007
9. DFMEA in accordance with Vesco Medical's design requirements

Clinical Tests

Clinical tests were not required to demonstrate performance of the Vesco Q™ Enteral Feeding Pump System. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests

Animal tests were not required to demonstrate the performance of the Vesco Q™ Enteral Feeding Pump System. Product functionality has been adequately assessed by non-animal tests.

IX. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Vesco Q™ Enteral Feeding Pump System is substantially equivalent to the EnteraLite Infinity™ Enteral Feeding Pump cleared under K031199 with respect to the indications for use, target populations, treatment method, and technological characteristics.