August 3, 2020

Vesco Medical LLC
Chris O'keefe
VP of Engineering
1039 Kingsmill Pkwy
Columbus, OH 43229

Re: K192991
Trade/Device Name: Vesco Medical Extension Feeding Set
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: July 6, 2020
Received: July 8, 2020

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192991

Device Name
Vesco Medical Extension Feeding Sets

Indications for Use *(Describe)*

The Vesco Medical Extension Feeding Sets are intended for use as an extension set to other gastric feeding devices, incorporating safety connectors which may reduce the risk of accidental connection of an IV system to the enteral system, or the enteral system to the IV system.

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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Tab 6
510(k) Summary

I. Submitter

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

Vesco Medical
Address: 1039 Kingsmill Parkway
Columbus, Ohio 43229

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

Date of Preparation July 6, 2020

II. Device

Trade Name: Vesco Medical Extension Feeding Sets

Common Name: Extension Feeding Set

Regulation Name: Gastrointestinal tube and accessories

Regulation Number: 21 CFR 876.5980

Device Classification: Class II

Device Classification/ Product Code: Gastrointestinal Tubes with Enteral Specific Connectors/ PIF

III. Legally Marketed Predicate Devices

- Aquarius Extension Feeding Sets were cleared under notification K141631 (510k application by Degania Silicone, Inc.)
    - Product name: Aquarius Extension Feeding Set
    - 510(k) Number: K141631
    - Manufacturer: Degania Silicone

- Product Code: KNT
- Device Class: Class II

IV. Device Description

The Vesco Medical Extension Feeding Set product line is comprised of a group of enteral tubes that will be used by trained caregivers for the delivery of nutrition and water. The Extension Sets will be used in a hospital or home environment. The Extension Sets will be provided non-sterile and are for single patient use. The Extension Sets will incorporate a male ENFit connector which is compatible with syringes and other devices that have female ENFit connectors. The ENFit connectors are being implemented within enteral feeding devices to eliminate misconnection with non-enteral feeding devices.

The Vesco Medical Extension Feeding Sets are non-sterile, single patient use devices consisting of a polyvinylchloride tube, ABS G-button connector, ENFit connector, cap and clamp. 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 G-button connectors are to allow compatibility to the Mic-key and Mini low profile devices. The proposed models are listed in Table 6.1.

The Vesco Medical Extension Feeding Set is substantially equivalent to the predicate device. The hollow tube and funnel are made of medical grade Polyvinylchloride (PVC). The low-profile G-button connector and the ENFit connector are made from acrylonitrile butadiene styrene. There are no changes in intension of use, product design, specification, functional performance, labels and instructions of use.

Table 6.1 Proposed models of Vesco Medical Extension Feeding Sets

Vesco Medical Extension Feeding Sets	
Model #	**Description**
VED-1000	12 Inch Dual ENFit Port Right Angle Extension Feeding Set
VED-1001	24 Inch Dual ENFit Port Right Angle Extension Feeding Set
VED-1002	12 Inch Single ENFit Port Straight Extension Feeding Set
VED-1003	24 Inch Single ENFit Port Straight Extension Feeding Set

V. Intended Use

Vesco Medical Extension Sets are intended to be used with low profile gastrointestinal button devices to deliver enteral nutrition or water to patients.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed Vesco Medical Extension Feeding Sets are the same manufactured products as the predicate. Because of this, there are no changes in the form, function, materials, or manufacturing processes from the predicate devices currently on the market. These products also have identical uses and user profiles. Table 6.2 is a comparison summary of the proposed device with the predicate. Table 6.3 lists the comparison of the proposed device to the predicate devices regarding substantial equivalence.

Table 6.2 Comparison Summary between Vesco Medical Extension Feeding Sets and the Predicate Device

Proposed Device Number	Device Description	Predicate Device Number	Differences in Design	Differences in Material	Differences in Chemical Composition	Differences in Energy Sources	Difference in Biocompatibility	Difference in Manufacturing
VED-1000	12 Inch Dual ENFit Port Right Angle Extension Feeding Set	1032531076VS	None- Devices are identical in dimensions and function	None - Devices are of the same materials	None - Devices are of the same material from the same source	None - Both rely on the same externally connected devices for fluid flow	None - Both devices have same material composition and require the same biocompatibility testing	None - Both devices are manufactured using the same manufacturing processes
VED-1001	24 Inch Dual ENFit Port Right Angle Extension Feeding Set	1032561076VS	None- Devices are identical in dimensions and function	None - Devices are of the same materials	None - Devices are of the same material from the same source	None - Both rely on the same externally connected devices for fluid flow	None - Both devices have same material composition and require the same biocompatibility testing	None - Both devices are manufactured using the same manufacturing processes
VED-1002	12 Inch Single ENFit Port Straight Extension Feeding Set	103290076VS	None- Devices are identical in dimensions and function	None - Devices are of the same materials	None - Devices are of the same material from the same source	None - Both rely on the same externally connected devices for fluid flow	None - Both devices have same material composition and require the same biocompatibility testing	None - Both devices are manufactured using the same manufacturing processes
VED-1003	24 Inch Single ENFit Port Straight Extension Feeding Set	1032960076VS	None- Devices are identical in dimensions and function	None - Devices are of the same materials	None - Devices are of the same material from the same source	None - Both rely on the same externally connected devices for fluid flow	None - Both devices have same material composition and require the same biocompatibility testing	None - Both devices are manufactured using the same manufacturing processes

Table 6.3 Comparison of Aquarius Medical Extension Feeding Sets to the Predicate Device Regarding Substantial Equivalence (SE)

Design Features/ Function	AQUARIUS Extension Feeding Set K141631 (Predicate)	Vesco Medical Extension Feeding Sets (Proposed)	Substantial Equivalence
Indications for Use	AQUARIUS Extension Feeding Set is intended for use as an extension set for AQUARIUS G-button/or other gastric feeding device, incorporating safety connectors which help mitigate the risk of accidental connection of an IV system to the enteral system, or the enteral system to IV system.	The Vesco Extension Feeding Sets are intended for use as an extension set to other gastric feeding devices, incorporating safety connectors which may reduce the risk of accidental connection of an IV system to the enteral system, or the enteral system to the IV system.	Substantially Equivalent
Environment of Use	Hospital or home	Hospital or home	Same
Patient Population	Patients 1 year and up	Patients 1 year and up	Same
Single Patient Use	Yes	Yes	Same
Sterility Condition	Sterile or Non-Sterile	Non-Sterile	Substantially Equivalent;
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; compliant with ISO 80369-3	Yes; compliant with ISO 80369-3	Same
Connector/Clamp Materials	All connectors and clamps are made with Acrylonitrile Butadiene Styrene	All connectors and clamps are made with Acrylonitrile Butadiene Styrene	Same
Description	-single or dual port -12 or 24 inch -continuous or bolus feed -straight or 90 degree port -stop clamp	-single or dual port -12 or 24 inch -continuous or bolus feed -straight or 90 degree port -stop clamp	Same
Biocompatibility	Biocompatibility testing has demonstrated that this device meets guidelines presented in 10993-1:2009 per K141631	Same materials, manufacturer, manufacturing materials and processes as predicate. Same product as predicate	Same
Tensile Strength Testing	Per K141631, results demonstrated the compliance with the	Same as predicate. Compliant with EN	Same

	performance and functionality specification of the device	1615:2000 and EN 1618:1997	
Flow Rate Testing	Per K141631, results demonstrated the compliance with the performance and functionality specification of the device	Same product as predicate.	Substantially Equivalent
Leakage Testing	Per K141631, results demonstrated the compliance with the performance and functionality specification of the device	Same as predicate. Compliant with EN 1615:2000 and EN 1618:1997	Same
Non IV compatible	80369-1 Annex B, AAMI/ANSI ID54 demonstrated non-compatibility of the proposed device with female luer connectors and intravenous sets	Same product as predicate. Compliant with ISO 80369-3	Substantially Equivalent
Labeling	Sold as “Vesco Medical Extension Feeding Sets”	Sold as “Vesco Medical Extension Feeding Sets”	Same

VII. Performance Data

Non-Clinical Tests

Verification and validation testing were performed with the Vesco Medical Extension Feeding Sets. It was found that the extension sets are in compliance with all design and performance requirements based on the completed testing below

1. Biocompatibility testing
    a. Cytotoxicity in accordance with ISO 10993-5:2009
    b. Guinea Pig Maximization Sensitization in accordance with ISO 10993-10:2010
    c. Irritation in accordance with ISO 10993-10:2010
    d. Acute Systemic Toxicity in accordance with ISO 10993-11:2017
    e. Subacute/Subchronic Toxicity in accordance with ISO 10993-11:2017
    f. Material-Mediated Pyrogenicity in accordance with ISO 10993-11:2017
2. Visual inspections/accelerated aging

   a. Visual inspection for cracks, deformation, or other visual abnormalities created during accelerated aging test per ASTM F1980-07.

3. Performance test
   a. Flowrate testing in accordance with Vesco Medical's design requirement.
   b. Pressure leak testing in accordance with EN1615:2000 and EN1618:1997.
   c. Tensile test in accordance with EN1615:2000 and EN1618:1997.
4. Cleaning Instructions Validation testing in accordance with CDRH's Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
5. Declaration of Conformance to applicable parts to ISO 80369.
6. Risk Analysis in accordance with ISO 14971:2012.
7. DFMEA in accordance with Vesco Medical's design requirements.

Clinical Tests

Clinical tests were not required to demonstrate performance of the Vesco Medical Extension Feeding Sets. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests

Animal tests were not required to demonstrate the performance of Vesco Medical Extension Feeding Sets. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Vesco Medical Extension Feeding Sets are as safe, as effective and perform as well as the legally marketed devices identified in part III, "Legally Marketed Predicate Devices" of this section.

(End of Section)