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

September 26, 2017

Vesco Medical, LLC
Rachel Kunzweiler
Product Development Engineer
692 N. High Street, Suite 205
Columbus, OH 43215

Re: K170162
Trade/Device Name: Vesco Medical Nasoenteric Feeding Tubes
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF
Dated: August 31, 2017
Received: August 31, 2017

Dear Rachel Kunzweiler:

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 (DICE) 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 (DICE) 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K170162

Device Name
Vesco Medical Nasoenteric Feeding Tubes

Indications for Use *(Describe)*

The Vesco Medical Nasoenteric Feeding Tubes (NE Tubes), with and without flow-through stylet, are for the administration of nutrition, fluids, and medications to the stomach or small bowel by the nasoenteric route in pediatric, adult or elderly patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition. The Vesco Medical Nasoenteric Feeding Tubes have not been tested for use longer than short-term use (<30 days).

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 5
510(k) Summary

I. Submitter

Official Contact

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Date of Preparation September 24, 2017

II. Device

Name of Device: Vesco Medical Nasoenteric Feeding Tubes

Common/Usual Name: Gastrointestinal Tubes

Device Classification: Class II

Classification Name/ Product Code: Gastrointestinal Tubes and Accessories (21 CFR 876.5980) / PIF

III. Legally Marketed Predicate Devices

- Covidien *Dobbhoff™ Dual Port Feeding Tubes* were most recently cleared under notification K112511.
- Ross Product Division Abbott Laboratories *Flexiflo Enteral Feeding Tubes* were most recently cleared under notification K992494.

IV. Device Description

The Vesco Medical Nasoenteric Feeding Tubes (NE Tubes) are non-sterile, single use devices consisting of flexible, radiopaque, polyurethane tubing adhered to a plastic male ENFit single-port connector with a tethered, twist-on cap. The plastic ENFit port allows for connection to enteral feeding sets and enteral-specific syringes while reducing the likelihood of misconnections to non-enteral devices. The cap allows for port coverage when enteral devices are not in use. The distal tip of the tubing is open and has four (4) evenly spaced, alternating eyelet openings to allow for fluid flow. The first three inches of the distal tip

are coated with a hydrophilic lubricant to aid in friction reduction during tube insertion. The tubing is printed with graduated markings indicating, in centimeters, the length from the distal tip in order to provide users with approximate insertion depth information. Certain models of the Vesco Medical Nasoenteric Feeding tube are provided with a stylet wire attached to a flow-through, ENFit hub. The stylet wire is intended to stiffen the tube during insertion and be removed after insertion is complete. The proposed device will be offered in sizes ranging between 8 French and 14 French.

V. Intended Use

The Vesco Medical Nasoenteric Feeding Tubes (NE Tubes), with and without flow-through stylet, are for the administration of nutrition, fluids, and medications to the stomach or small bowel by the nasoenteric route in pediatric, adult or elderly patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition. The Vesco Medical Nasoenteric Feeding Tubes have not been tested for use longer than short-term use (<30 days).

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed Vesco Medical Nasoenteric Feeding Tubes and the predicate devices are all intended for administering nutrition, fluids, and medications through the nastoenteric route to the stomach or small bowel of patients unable to manage nutritional intake through normal mastication and deglutition. These products have similar intended uses, technological characteristics, manufacturing methods, and operating principles. There are no significant differences that would affect the performance of the Vesco Medical Nasoenteric Feeding Tubes as compared to the predicate devices. Table 5.1 lists the comparisons of the proposed device to the predicate devices.

Table 5.1: Comparison of Vesco Medical Nasoenteric Feeding Tubes to predicate devices regarding substantial equivalence (SE), similarities, and differences.

Design Features/Function of Proposed Device	Proposed Device Compared to Covidien Dobbhoff Dual Port Feeding Tubes K112511 (Predicate)	Proposed Device Compared to Ross Products Division Abbott Flexiflo Enteral Feeding Tubes K992494 (Predicate)
Intended Use	Similar and SE	Similar and SE
Environment of Use	Similar and SE	Similar and SE
Intended Users	Similar and SE	Similar and SE
Patient Population	Similar	Same
Single Use	Same	Same
Nonsterile	Same	Same
Stomach and Small Bowel Placement	Same	Same
ENFit Connector	Different (predicate has catheter slip-tip connector); no decrease in performance of proposed device	Different (predicate has catheter slip-tip connector)
Single Port	Different (predicate has dual port)	Different (predicate has dual port)
Flow-through Stylet Hub	Unknown	Different (predicate's hub is non-ENFit and of different material)
No Bolus Weight	Unknown	Similar (with or without bolus)
Radiopaque Tube Material	Similar and SE	Same
Hydrophilic Coating	Similar and SE	Same
Markings on Tube for Measuring Inserted Length	Similar and SE	Same

Used With or Without Stylet	Similar and SE	Same
French Sizes	Same	Same
Lengths	Similar and SE	Same

VII. Performance Data:

Non-Clinical Tests

Verification and validation Testing was performed with the Vesco Medical Nasoenteric Feeding Tubes. It was found that Vesco Medical Nasoenteric Feeding Tubes are in compliance with design and performance requirements according to ISO 80369 “Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications,” and EN1615:2000 “Enteral feeding catheters and enteral giving sets for single use and their connectors: Design and Testing.” Additionally, Vesco Medical Nasoenteric Feeding Tubes that underwent accelerated aging conditioning were tested in order to substantiate an eighteen (18) month shelf life.

The following testing was conducted on the Vesco Medical Nasoenteric Feeding Tubes:

1. Biocompatibility Testing per ISO-10993-1 and ISO 10993-5
    a. Cytotoxicity performed per ISO-10993-5 on Vesco Medical Nasoenteric Feeding Tubes
    b. Cytotoxicity, intracutaneous, and maximization sensitization testing reports provided by Cedic for component with same materials, manufacturer, and manufacturing process as stylet hub.
    c. Additional biocompatibility testing for the ENFit connector material and colorant leveraged from Cedic’s previously cleared K140581.
    d. Remaining biocompatibility testing leveraged from K992494 due to material and manufacturing equivalence (stylet wire, tubing, ink, lubricant, and adhesive).
2. Visual and Physical Inspections
    a. Visual inspection for bleeding of tube ink markings per Vesco Medical Design Requirement
    b. Visual inspection for legibility of tube ink markings per Vesco Medical Design Requirement
    c. Visual inspection for cracks or delamination of the lubricous coating per Vesco Medical Design Requirement
    d. Physical inspection for water activation of lubricious coating per Vesco Medical Design Requirement
    e. Visual Inspection for adequate adhesion between extruded NE Tube and ENFit connector per Vesco Medical Design Requirement
    f. Patency of stylet per Vesco Medical Design Requirement
    g. Stylet removal force per Vesco Medical Design Requirement
3. Patency of NE Tubes/flow rate testing (compared against predicate)
    a. Using water
    b. Using nutritional fluid
4. Leakage Testing per EN1615:2000 & EN1618:1997
5. Tensile Testing per EN1615:2000 & EN1618:1997
6. Resistance to Kinking per EN1615:2000 & EN 13868:2002, against predicate
7. Fluid Leakage per ISO 80369-3:2016, performed by Cedic
8. Stress Cracking per ISO 80369-3:2016, performed by Cedic
9. Resistance to separation from axial load ISO 80369-3:2016, performed by Cedic
10. Resistance to separation from unscrewing per ISO 80369-3:2016, performed by Cedic
11. Resistance to overriding per ISO 80369-3:2016, performed by Cedic
12. Disconnection by unscrewing per ISO 80369-3:2016, performed by Cedic
13. ENFit dimensional verification per ISO 80369-3:2016, performed by Cedic

14. Risk Analysis per ISO 14971:2012
15. Design Failure Modes and Effects Analysis (DFMEA)

Clinical Tests

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

Animal Tests

Animal tests were not required to demonstrate the performance of Vesco Medcical Nasoenteric Feeding Tubes. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Vesco Medical Nasoenteric Feeding tubes are as safe, as effective, and perform as well as or better than the legally marketed devices identified in part III, “Legally Marketed Predicate Devices” of this section.