



June 9, 2022

Cair Lgl
% Glenn Brunner
Dir. Regulatory Affairs and Quality Assurance
Vesco Medical
1039 Kingsmill Parkway
Columbus, OH 43229

Re: K213258
Trade/Device Name: Nasogastric Feeding Tubes - ENFit Port - PVC
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: May 11, 2022
Received: May 13, 2022

Dear Glenn Brunner:

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,

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

Indications for Use

510(k) Number (if known)
K213258

Device Name
Nasogastric Feeding Tubes - ENFit Port - PVC

Indications for Use (Describe)

The Nasogastric Feeding Tubes - ENFit Port - PVC are intended for enteral feeding to deliver nutrition, fluids, and medications to the patient from an enteral feeding syringe or feeding set designed with ENFit connectors for enteral applications.

This product is single use for no longer than 24 hours.

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
PRASStaff@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."

Tab 5A 510(k) Summary

I. Submitter

Official Contact

Name: Glenn Brunner
Title: Dir. Regulatory Affairs and Quality Assurance
Email: gbrunner@vescomedical.com

Vesco Medical
Address: 1039 Kingsmill Parkway
Columbus, Ohio 43229

Phone: 614-946-4178 (mobile)
Fax: 614-515-2800

Date of Preparation

June 6, 2022

II. Device

Trade Name: Nasogastric Feeding Tubes – ENFit Port - PVC
Common Name: Nasogastric Tubes
Classification Name & Number: Gastrointestinal Tubes and Accessories
21 CFR 876.5980
Class II
Product Code: PIF

III. Legally Marketed Predicate Device

Product name: Argyle™ Polyvinyl Chloride (PVC) and Kangaroo™ Polyurethane (PU)
Neonatal and Pediatric Feeding Tubes with ENFit connector

510(k) Number: K150084

Manufacturer: Covidien

Product Code: PIF

Device Class: Class II

IV. Device Description

General Description of Nasogastric Feeding Tubes – ENFit Port - PVC

The Nasogastric Feeding Tubes – ENFit Port - PVC are sterile, single use devices. The feeding tubes consist of a graduated polyvinyl chloride tube, with radiopaque edge. The tubes have a closed tip and two lateral eyes for Fr sizes 5 to 10 and three lateral eyes for Fr sizes 12 to 16. The tubes have at the other end an ENFit male connector in ABS with its Polypropylene cap. A tether in thermoplastic polyurethane connects the ENFit connector to its cap. The ENFit connector allows the device to be connected to female enteral devices that have an ISO 80369-3 compliant connector. The feeding tubes are available in 50cm and 90cm lengths and in French sizes from 5 to 16 see Table 5-1.

Table 5-1: Models of Nasogastric Feeding Tubes

Nasogastric Feeding Tubes – ENFit Port - PVC		
Model	Tube Size	Device Length
VED-95005EO	5 Fr	50 cm
VED-99005EO	5 Fr	90 cm
VED-95006EO	6 Fr	50 cm
VED-99006EO	6 Fr	90 cm
VED-95008EO	8 Fr	50 cm
VED-99008EO	8 Fr	90 cm
VED-95010EO	10 Fr	50 cm
VED-99010EO	10 Fr	90 cm
VED-99012EO	12 Fr	90 cm
VED-99014EO	14 Fr	90 cm
VED-99016EO	16 Fr	90 cm

V. Intended Use

The Nasogastric Feeding Tubes – ENFit Port – PVC are intended for hydration, feeding and administration of oral medications for patients who require enteral feeding. This product is single use for no longer than 24 hours.

VI. Substantial Equivalence Discussion

The Nasogastric Feeding Tubes – ENFit Port - PVC are substantially equivalent to the currently marketed predicate Feeding Tube. Table 5-2 is a detailed comparison of the Cair feeding tubes to the predicate devices regarding substantial equivalence.

Table 5-2: Device comparison table for Nasogastric Feeding Tubes – ENFit Port - PVC and the predicate device.

Design Features/Function	Argyle Polyvinyl Chloride Feeding Tube, K150084 (Predicate)	Nasogastric Feeding Tubes –ENFit Port - PVC	Substantially Equivalent?	Impact on Safety and Performance
Indications for Use	The Argyle Polyvinyl Chloride (PVC) Neonatal and Pediatric Feeding Tubes with ENFit connectors are intended for enteral feeding to deliver enteral nutrition, liquid or medication to patient from an enteral feeding syringe or feeding set designed with a connector for enteral applications.	The Nasogastric Feeding Tubes - ENFit Port - PVC are intended for enteral feeding to deliver nutrition, fluids, and medications to the patient from an enteral feeding syringe or feeding set designed with ENFit connectors for enteral applications. This product is single use for no longer than 24 hours.	Yes	Equivalent to K150084. There are no differences in indications for use that would impact the safety and performance of the device.

Intended Use	The Argyle Polyvinyl Chloride Feeding Tube is intended for pediatric patients who require enteral feeding. (Warning: The Polyvinyl Chloride feeding tube is not intended for use beyond 3-5 days)	The Nasogastric Feeding Tubes – ENFit Port – PVC are intended for hydration, feeding, and administration of oral medications for pediatric and adult patients who require enteral feeding. This product is single use for no longer than 24 hours.	Yes	Equivalent to K150084. There are no differences in intended use that would impact the safety and performance of the device.
Environment of Use	Unspecified – Prescription Only	Hospital or medical home environment – Prescription Only	Yes	Equivalent to K150084. There are no differences in environment of use that would impact the safety and performance of the device.
Intended Users	Trained professional clinicians or trained pediatric caregivers.	Physicians, nurses, and trained clinicians (by facility policy)	Yes	Equivalent to K150084. There are no differences in intended users that would impact the safety and performance of the device
Patient Population	Pediatric patients	Pediatric and Adult patients	Yes	Similar to K150084. There are no differences in patient population that would impact the safety and performance of the device
Single Use	Yes	Yes	Yes	Equivalent to K150084. No impact on safety or performance

Traditional 510(k)

Nasogastric Feeding Tubes – ENFit Port - PVC

Sterility Condition	Sterile	Sterile	Yes	Equivalent to K150084. No impact on safety or performance
ENFit Connector	Yes; compliant with ISO 80369-3	Yes; compliant with ISO 80369-3	Yes	Equivalent to K150084. No impact on safety or performance
Radiopacity Verification	Yes	Yes; compliant with ISO 20695:2020	Yes	Equivalent to K150084. No impact on safety or performance
Tube Markings	Yes	Yes; compliant with ISO 20695:2020	Yes	Equivalent to K150084. No impact on safety or performance
French Sizes	3.5, 5, 6.5, 8, 10	5, 6, 8, 10, 12, 14, 16	Yes	Similar to K150084. No impact on safety or proper performance
Lengths	41cm, 91cm, 107cm	50cm, 90cm	Yes	Similar to K150084. No impact on safety or proper performance
Biocompatibility	Compliant with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"	Compliant with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"	Yes	Equivalent to K150084. No impact on safety or performance
Liquid Leakage Testing	Liquid Leakage Testing Completed (e.g. EN 1615:2000)	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K150084. No impact on safety or performance

Traditional 510(k)

Nasogastric Feeding Tubes – ENFit Port - PVC

Tensile Testing	Tensile Testing Completed (e.g. EN 1615:2000)	Tested and met updated standard ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K150084. No impact on safety or performance
Flow Rate Testing	Flow Rate Testing Completed per substantial equivalence to predicate device	Tested per ISO 20695:2020 Enteral Feeding Systems – Design and Testing	Yes	Equivalent to K150084. No impact on safety or performance
Fluid Leakage: Connector	Tested per ISO 80369-20 and met the standards of 80369-3 for fluid leakage.	Tested per ISO 80369-20 and met the standards of 80369-3 for fluid leakage.	Yes	Equivalent to K150084. No impact on safety or performance
Stress Cracking: Connector	Tested per ISO 80369-20 and met the standards of 80369-3 for stress cracking.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for stress cracking.	Yes	Equivalent to K150084. No impact on safety or performance
Resistance to separation from axial load: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for resistance to separation from axial load.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance to separation from axial load.	Yes	Equivalent to K150084. No impact on safety or performance
Resistance to separation from unscrewing: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for separation from unscrewing.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for separation from unscrewing.	Yes	Equivalent to K150084. No impact on safety or performance
Resistance to overriding: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for resistance to overriding.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance to overriding.	Yes	Equivalent to K150084. No impact on safety or performance

Disconnection by unscrewing: connector	Tested per ISO 80369-20 and met the standards of 80369-3 for disconnection by unscrewing.	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for disconnection by unscrewing.	Yes	Equivalent to K150084. No impact on safety or performance
ENFit Dimensional Verification	Evaluated per ISO 80369-3 for ENFit dimensional verification.	Evaluated per ISO 80369-3 for ENFit dimensional verification.	Yes	Equivalent to K150084. No impact on safety or performance

VII. Discussion of Differences

There are no substantial differences between the indications for use, use conditions, and use environment of the predicate devices and the Nasogastric Feeding Tubes – ENFit Port - PVC.

VIII. Performance Testing

Non-Clinical Tests

Verification and validation testing was performed with the Nasogastric Feeding Tubes – ENFit Port - PVC. It was found that feeding tubes are in compliance with the design and performance requirements when tested per the standards listed below.

1. Biocompatibility:
 - a. Cytotoxicity per ISO 10993-5:2009
 - b. Guinea Pig Maximization Sensitization per ISO 10993-10:2010
 - c. Irritation per ISO 10993-10:2010
 - d. Acute Systemic Toxicity per ISO 10993-11:2017
 - e. Material-Mediated Pyrogenicity per 10993-11:2017
2. Visual Inspections
 - a. Visual inspection for verification of bonding
3. Enteral Device Performance test
 - a. Pressure leak testing in accordance with ISO 20695:2020
 - b. Tensile testing in accordance with ISO 20695:2020
 - c. Resistance of the tube marking to acid in accordance with internal protocol

- d. Resistance of the tube marking to disinfectants in accordance with ISO 20695:2020
 - e. Visibility of enteral tube under x-ray in accordance with internal protocol based on ASTM F640-12
 - f. Flow rate testing in accordance with ISO 20695:2020
4. Enteral Connector Performance Tests
 - a. Fluid leakage per ISO 80369-20:2019
 - b. Stress cracking per ISO 80369-20:2019
 - c. Resistance to separation from axial load per ISO 80369-20:2019
 - d. Resistance to separation from unscrewing per ISO 80369-20:2019
 - e. Resistance to overriding per ISO 80369-20:2019
 - f. Disconnection by unscrewing per ISO 80369-20:2019
 - g. ENFit dimensional verification per ISO 80369-3:2016
 5. Risk Analysis per ISO 14971:2019.
 - a. Design Failure Modes and Effects Analysis (DFMEA).
 6. Usability Analysis per ISO 62366-1:2015.

Clinical Tests

Clinical tests were not required to demonstrate the safety and performance of the Nasogastric Feeding Tubes – ENFit Port - PVC. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests

Animal tests were not required to demonstrate the safety and performance the Nasogastric Feeding Tubes – ENFit Port - PVC. Product functionality has been adequately assessed by non-animal tests.

IX. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Nasogastric Feeding Tubes – ENFit Port - PVC are substantially equivalent in safety and effectiveness to the legally marketed devices identified in part III, “Legally Marketed Predicate Devices” of this section.

(End of Section)