November 2, 2023

Vesco Medical
Glenn Brunner
Dir. Regulatory Affairs and Quality Assurance
60 Collegeview Road, Suite 144
Westerville, Ohio 43081

Re: K230326
Trade/Device Name: ENFit to ENFit Extension Sets
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: January 31, 2023
Received: February 6, 2023

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 (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,

Sivakami Venkatachalam -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230326

Device Name
ENFit to ENFit Extension Sets

Indications for Use *(Describe)*
The ENFit to ENFit Extension Sets are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition, fluids and medications from an enteral feeding syringe or set through to an ENFit feeding tube connector for enteral applications.

The device is single use for patients who require enteral feeding.

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."

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: 60 Collegeview Road, Suite 144
Westerville, Ohio 43081

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

Date of Preparation October 2, 2023

II. Device

Trade Name:	ENFit to ENFit Extension Sets
Common Name:	Extension Feeding Set
510(k) Number:	K230326
Classification Name & Number:	Gastrointestinal Tubes with Enteral Specific Connectors 21 CFR 876.5980 Class II Product Code: PIF

III. Legally Marketed Predicate Device

Product name: Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors

510(k) Number: K143018

Manufacturer: Covidien (Cardinal Health)

Product Code: PIF

Device Class: Class II

IV. Device Description

General Description of The ENFit to ENFit Extension Sets

The ENFit to ENFit Extension Sets are sterile, single use devices. The extension sets are single and bifurcated port tubing sets with ENFit input port(s) and tethered caps, extension set tubing and clamp(s), and a single ENFit connector on the patient end. The ENFit connectors allow the extension set to be connected to other enteral devices that also have ISO 80369-3 compliant connectors. The extension sets are available in the listed lengths from 50 to 150 cm.

Table 5-1: Models of ENFit to ENFit Extension Sets

ENFit to ENFit Extension Sets			
Model	**Type**	**Device Length**	**I.D.**
VED–1020EO	Bifurcated ENFit Ports to ENFit Extension Set - Sterile	20 in - 50 cm	2.8 mm
VED–1040EO	Single ENFit Port to ENFit Extension Set - Sterile	39 in - 100 cm	2.8 mm
VED-1059EO	Co-Extruded Single ENFit Port to ENFit Extension Set - Sterile	59 in - 150 cm	1.35 mm
VED-1060EO	Bifurcated ENFit Ports to ENFit Extension Set - Sterile	59 in - 150 cm	2.8 mm

V. Intended Use

The ENFit to ENFit Extension Sets are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition, fluids and medications from an enteral feeding syringe or set through to an ENFit feeding tube connector for enteral applications.
The device is single use for patients who require enteral feeding.

VI. Substantial Equivalence Discussion

The ENFit to ENFit Extension Sets are substantially equivalent to the currently marketed predicate extension sets. Table 5-2 is a detailed comparison of the Vesco extension sets to the predicate devices regarding substantial equivalence.

Table 5-2: Device comparison table for ENFit to ENFit Extension Sets and the predicate device.

Design Features/Function	**Kangaroo™ Feeding Tube Extension Sets with ENFit Small Bore Connectors, K143018** **(Predicate)**	**ENFit to ENFit Extension Sets**	**Substantially Equivalent?**	**Impact on Safety and Performance**
Indications for Use	The Kangaroo™ Feeding Tube Extension Sets with ENFit small bore connectors are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition or medication from an enteral feeding syringe through to any feeding tube which will accept a connector for enteral applications. The device is intended for neonates and infants who require enteral feeding.	The ENFit to ENFit Extension Sets are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition, fluids and medications from an enteral feeding syringe or set through to an ENFit feeding tube connector for enteral applications. The device is single use for patients who require enteral feeding.	Yes	Equivalent to K143018. There are no differences in indications for use that would impact the safety and performance of the device.

Intended Use	The Kangaroo™ Feeding Tube Extension Sets with ENFit small bore connectors are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition or medication from an enteral feeding syringe through to any feeding tube which will accept an ENFit small bore connector for enteral applications. The device is intended for neonates and infants who require enteral feeding.	The ENFit to ENFit Extension Sets are intended for enteral feeding, on the order of a physician, to provide a means of delivering enteral nutrition, fluids and medications from an enteral feeding syringe or set through to an ENFit feeding tube connector for enteral applications. The device is single use for patients who require enteral feeding.	Yes	Equivalent to K143018. There are no differences in intended use that would impact the safety and performance of the device.
Environment of Use	Hospital, sub-acute care and home settings.	Hospital or medical home care environment – Prescription Only	Yes	Equivalent to K143018. 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 K143018. There are no differences in intended users that would impact the safety and performance of the device
Patient Population	Neonatal and pediatric patients	Pediatric and Adult patients	Yes	Similar to K143018. There are no differences in patient population that would

				impact the safety and performance of the device
No Reuse	Single Patient Use	Single Use	Yes	Equivalent to K143018. No impact on safety or performance
Sterility Condition	Sterile	Sterile	Yes	Equivalent to K143018. No impact on safety or performance
ENFit Connector	Yes; compliant with ISO 80369-3	Yes; compliant with ISO 80369-3	Yes	Equivalent to K143018. No impact on safety or performance
Lengths	35” to 60” (90 to 150 cm)	50cm, 100cm, 150cm	Yes	Similar to K143018. 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 K143018. 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 K143018. 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 K143018. No impact on safety or performance
Resistance to separation from	Tested per ISO 80369-20 and met the standards of 80369-3 for	Tested per ISO 80369-20 and met the standards of ISO 80369-3 for resistance	Yes	Equivalent to K143018. No impact

axial load: connector	resistance to separation from axial load.	to separation from axial load.		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 K143018. 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 K143018. 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 K143018. 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 K143018. 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 ENFit to ENFit Extension Sets.

VIII. Performance Testing

Non-Clinical Tests

Verification and validation testing was performed with the ENFit to ENFit Extension Sets. It was found that extension sets are in compliance with the design and performance requirements when tested according to 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. 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 ENFit to ENFit Extension Sets. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests

Animal tests were not required to demonstrate the safety and performance the ENFit to ENFit Extension Sets. Product functionality has been adequately assessed by non-animal tests.

IX. Conclusion

The conclusions drawn from the non-clinical tests and other presented analyses demonstrate that the ENFit to ENFit Extension Sets are substantially equivalent to the legally marketed predicate device and do not raise new questions of safety and effectiveness.

(End of section)