November 2, 2021

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

Re: K210598
Trade/Device Name: Pediatric Nasogastric Feeding Tubes - Single ENFit Port
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: September 26, 2021
Received: September 29, 2021

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

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)*
K210598

Device Name
Pediatric Nasogastric Feeding Tubes - Single ENFit Port

Indications for Use *(Describe)*

The Pediatric Nasogastric Feeding Tubes - Single ENFit Port 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 29 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.**

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

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# 510(k) Summary

## I. Submitter

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**Official Contact**

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**Date of Preparation** February 17, 2021

## II. Device

| | |
|---|---|
| **Trade Name:** | Pediatric Nasogastric Feeding Tubes – Single ENFit Port |
| **Common Name:** | Nasogastric Tubes |
| **Classification Name & Number:** | Gastrointestinal Tubes with Enteral Specific Connectors<br>21 CFR 876.5980<br>Class II<br>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 Pediatric Nasogastric Feeding Tubes – Single ENFit Port**

The Pediatric Nasogastric Feeding Tubes – Single ENFit Port are sterile, single use devices. The feeding tubes consist of a graduated Polyurethane tube, with radiopaque edge. The tubes have a closed tip and 2 lateral eyes. 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 40mm, 60mm and 90mm lengths and in French sizes from 4 to 12 see Table 5.1.

**Table 5.1:** Models of Pediatric Nasogastric Feeding Tubes

| **Pediatric Nasogastric Feeding Tubes – Single ENFit Port** | | |
|---|---|---|
| **Model** | **Tube Size** | **Device Length** |
| VED–84004EO | 4 Fr | 40 mm |
| VED–86004EO | 4 Fr | 60 mm |
| VED-84005EO | 5 Fr | 40 mm |
| VED-86005EO | 5 Fr | 60 mm |
| VED-86006EO | 6 Fr | 60 mm |
| VED-89006EO | 6 Fr | 90 mm |
| VED-86008EO | 8 Fr | 60 mm |
| VED-89008EO | 8 Fr | 90 mm |
| VED-86010EO | 10 Fr | 60 mm |
| VED-89010EO | 10 Fr | 90 mm |
| VED-89012EO | 12 Fr | 90 mm |

# V. Intended Use

The Pediatric Nasogastric Feeding Tubes – Single ENFit Ports are intended for hydration, feeding and administration of oral medications for pediatric patients who require enteral feeding. This product is single use for no longer than 29 days.

# VI. Substantial Equivalence Discussion

The Pediatric Nasogastric Feeding Tubes – Single ENFit Port 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** Comparison of Cair Feeding Tubes to the Predicate Devices Regarding Substantial Equivalence (SE)

| **Design Features/Function** | **Kangaroo Polyurethane Feeding Tube, K150084**<br><br>**(Predicate)** | **Pediatric Nasogastric Feeding Tubes – Single ENFit Port** | **Substantially Equivalent?** | **Impact on Safety and Performance** |
|---|---|---|---|---|
| Indications for Use | The Kangaroo Polyurethane 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 Pediatric Nasogastric Feeding Tubes - Single ENFit Port 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.<br><br>This product is single use for no longer than 29 days. | Yes | Equivalent to K150084.<br><br>There are no differences in indications for use that would impact the safety and performance of the device. |

| | | | | |
|---|---|---|---|---|
| Intended Use | The Kangaroo Polyurethane Feeding Tube is intended for pediatric patients who require enteral feeding.<br>(Warning: The Polyurethane feeding tube is not intended for use beyond 30 days) | The Pediatric Nasogastric Feeding Tubes – Single ENFit Ports are intended for hydration, feeding and administration of oral medications for pediatric patients who require enteral feeding. This product is single use for no longer than 29 days. | 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 | Neonatal and Pediatric patients | Neonatal and Pediatric 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 |
| 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 | 4, 5, 6, 8, 10, 12 | Yes | Similar to K150084. No impact on safety or proper performance |
| Lengths | 31cm, 51cm, 91cm, 107cm | 40cm, 60cm, 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 |
| 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 |
| 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 Pediatric Nasogastric Feeding Tubes – Single ENFit Port.

# VIII. Performance Testing

**Non-Clinical Tests**

Verification and validation testing was performed with the Pediatric Nasogastric Feeding Tubes – Single ENFit Port. It was found that the Pediatric Nasogastric Feeding Tubes are in compliance with all design and performance requirements based on the results of the results presented.

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 and Subacute Systemic Toxicity per ISO 10993-11:2017
    e. Material mediated pyrogenicity per USP<151>
2. 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.
3. Enteral Connector Performance Tests
    a. Fluid leakage testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    b. Stress cracking testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    c. Resistance to separation from axial load testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    d. Resistance to separation from unscrewing testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    e. Resistance to overriding testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    f. Disconnection by unscrewing testing in accordance with ISO 80369-3:2016 and ISO 80369-20:2015.
    g. ENFit dimensional verification testing in accordance with ISO 80369-3:2016

   h. Flow rate testing in accordance ISO 20695:2020, Annex E

4. Risk Analysis in accordance with ISO 14971:2019.
   a. DFMEA in accordance with product design requirements.

5. Usability Analysis in accordance with ISO 62366-1: 2015

**Clinical Tests**

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

**Animal Tests**

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

# IX. Conclusion

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