July 10, 2023

Vonco Products
Christie Marr
Sr. Director of Quality & Regulatory
10826 250th Avenue
Trevor, WI 53179

Re: K223683
Trade/Device Name: EnteraLoc Flow
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF
Dated: June 6, 2023
Received: June 6, 2023

Dear Christie Marr:

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 -S

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)*
K223683

Device Name
Vonco Products EnteraLoc Flow

Indications for Use *(Describe)*
The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector is indicated for use as a dispenser of enteral nutrition by way of direct connection to a feeding tube or extension set. It is intended to deliver nutrition into the gastrointestinal system of a patient. The pouch, once filled, is intended to be used in clinical or home care settings by users ranging from laypersons to clinicians, in all age groups.

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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5.1 Administrative Information

Date of Summary Preparation:	12/07/2022
Submitter:	Vonco Products, LLC 10826 250th Avenue Trevor, WI 53179 Phone: (800)323-9077 Fax: (262)298-7242
Primary Contact Information:	Christie Marr Senior Director of Quality & Regulatory 10826 250th Avenue Trevor, WI 53179 Phone: (262)298-7203 Email: christie@vonco.com
Secondary Contact Information:	Brian Young Vice President of Technical Engineering 10826 250th Avenue Trevor, WI 53179 Phone: (262)298-7236 Email: brian.young@vonco.com

5.2 Device Information

Trade Name:	EnteraLoc Flow
Common Name:	Gastrointestinal Tubes with Enteral Specific Connectors
Classification Name:	Gastrointestinal Tubes and Accessories
Regulation Number:	21 CFR 876.5980
Regulatory Class:	II
Product Code:	PIF
Panel:	Gastroenterology and Urology
Prior Submissions Related to Subject Device:	K210971

5.3 Predicate Device

The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector is substantially equivalent to the following devices:

- K210971 – EnteraLoc Flow
- K190310 – U Deliver Bolink ENFit Enteral Feeding Sets

5.4 Device Description

The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector consists of a foil pouch with an integrated female ENFit® connector at one end. The EnteraLoc Flow pouch is provided with a tamper evident cap. The pouch is designed to be pre-filled with liquid nutrition formula for tube feeding. EnteraLoc Flow is a single use device.

EnteraLoc Flow spouted pouch with ENFit® Connector is designed as a single use, over-the-counter device. The pouches will be available in a range of sizes, with a range of nutritional values (based upon the formula which the pouch is filled). Based upon the required nutritional intake requirements, the user will select the proper size pouch and quantity for feeding.

5.5 Indications for Use

The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector is indicated for use as a dispenser of enteral nutrition by way of direct connection to a feeding tube or extension set. It is intended to deliver nutrition into the gastrointestinal system of a patient. The pouch, once filled, is intended to be used in clinical or home care settings by users ranging from laypersons to clinicians, in all age groups.

5.6 Intended Use

The EnteraLoc Flow spouted pouch with ENFit® Connector is intended to deliver liquid nutrition feeding to an enteral access device.

5.7 Comparison of Technological Characteristics

The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector is intended to connect to male ENFit® connectors, including temporary transition sets and feeding tube administration sets. The disposable pouch is for single use and is designed such that the user can connect the pouch directly to a feeding tube.

The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector will be pre-filled with liquid nutrition formula, so the need for a syringe or feeding bag is not required. Having the liquid nutrition contained in the EnteraLoc Flow pouch eliminates the frequency of spills during transfer to these syringes or feeding bags. Liquid nutrition can be administered by hanging the pouch for gravity feeding or by gently squeezing the pouch to perform a bolus feeding.

A comparison of the proposed and predicate devices can be found in Table 5-1.

Table 5-1

Device Characteristics	Vonco Products Subject Device	Vonco Products Subject Device (K210971)	U Deliver Predicate (K190310)
Product Code	PIF	PIF	PIF
Regulation	876.5980	876.5980	876.5980
Indications for Use	Indicated for use as a dispenser of enteral nutrition by way of direct connection to a feeding tube or extension set. It is intended to deliver nutrition into the gastrointestinal system of a patient. The pouch, once filled, is intended to be used in clinical or home care settings by users ranging from laypersons to clinicians, in all age groups.	Indicated for use as a dispenser of enteral nutrition by way of direct connection to a feeding tube or extension set. It is intended to deliver nutrition into the gastrointestinal system of a patient. The pouch, once filled, is intended to be used in clinical or home care settings by users ranging from laypersons to clinicians, in all age groups.	Intended for over-the-counter use to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).
Intended Use	Is intended to deliver liquid nutrition formula to an enteral access device.	Is intended to deliver liquid nutrition formula to an enteral access device.	Intended for over-the-counter use to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).
User Population	Patients with enteral access devices, their clinicians, and caregivers.	Patients with enteral access devices, their clinicians, and caregivers.	They can be used for adults, children, infants, and neonates.
Type of Feeding	Gravity or Bolus	Gravity or Bolus	Gravity or Bolus
Design Characteristics	Foil Pouch with integrated female ENFit® Connector	Foil Pouch with integrated female ENFit® Connector	Cap with tube and integrated female ENFit® Connector designed to be interconnected to a reservoir for water or liquid nutrition formulas.
Device Materials	Laminated foil film Pouch, Polypropylene Cap and Spout	Laminated foil film Pouch, Polypropylene Cap and Spout	Not Available

Female ENFit® Connector	Meets ISO 80369-3	Meets ISO 80369-3	Meets ISO 80369-3
Biocompatibility	Meets ISO 10993-1	Meets ISO 10993-1	Meets ISO 10993-1
Sterilization	Non-Sterile	Non-Sterile	Sterile and Non-Sterile
Single-Use	Yes	Yes	Yes
Latex Free	Yes	Yes	Yes

The intended use of the subject device and predicate devices are similar in that they each are single use, disposable devices intended to provide liquid nutrition to a patient via a feeding tube. The subject device is provided non-sterile just as the Vonco predicate device (K210971) and the U Deliver predicate device (K190310). The principles of operation are the same. Each device employs a female ENFit® connector to connect directly to a male ENFit® connector on a feeding tube or extension set. The Vonco Products EnteraLoc Flow spouted pouch with ENFit® Connector and the Vonco predicate device (K210971) are the same in that they both eliminate the need to pre-fill the device prior to feeding, reducing the risk of spills and food contamination. The U Deliver predicate (K190310) connects to a reservoir similar to the EnteraLoc pouch to allow for direct feeding.

5.8 Performance Data

Vonco Products has conducted the following performance testing on the EnteraLoc Flow spouted pouch with ENFit® Connector:

- Flow Rate Analysis
- Biocompatibility Testing per ISO 10993-1:2019
  - Cytotoxicity
  - Irritation/Intracutaneous Reactivity
  - Sensitization
- Performance Testing per ISO 80369-3:2016
  - Dimensioning
  - Falling Drop Positive Pressure Liquid Leakage
  - Stress Cracking
  - Resistance to Separation from Axial Load
  - Resistance to Separation from Unscrewing
  - Resistance to Overriding
  - Disconnection by Unscrewing
- ISO 80369-1:2018 Misconnection Analysis
- Spouted Pouch Functional Testing
- Retort Suitability
- Stability Testing
- Risk Analysis for OTC suitability

5.9 Conclusion

In accordance with 21 CFR Part 807 and based on a comparison of 'Indications for Use', technological characteristics and performance data, Vonco Products, LLC concludes that the proposed EnteraLoc Flow spouted pouch with ENFit® Connector is substantially equivalent to the predicate devices, EnteraLoc Flow (K210971) and U Deliver Bolink ENFit Enteral Feeding Sets (K190310).