



**FOR IMMEDIATE RELEASE**

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## **U.S. FDA Approves Over-the-Counter Designation for Vonco's EnteraLoc™ Flow Direct-Connect Enteral Feeding Solution**

- EnteraLoc Flow is the first seamless, closed-loop enteral feeding solution that combines a spill-proof pouch, direct-connect ENFit® device, tube, and nutritious food options in one complete feeding system
- EnteraLoc Flow has been available by prescription since 2021
- Over-the-counter availability is anticipated later this year

**TREVOR, WI, September 18, 2023** – Vonco Products LLC, an industry-leading risk-free plastic and packaging manufacturer, is excited to announce the U.S. Food and Drug Administration (FDA) has cleared EnteraLoc Flow as an over-the-counter (OTC) direct-connect feeding solution for enteral patients.

Each year, more than 1 million patients in the United States are placed on feeding tubes to sustain life and/or improve healing. By offering EnteraLoc Flow as an OTC feeding solution, enterally fed individuals and their caregivers will be able to purchase it without a prescription – an important step in the fight to improve the health, mobility, and lifestyle of enteral patients by providing superior options for nutritional formulations and methods of delivery. EnteraLoc Flow was [granted 510\(k\) clearance \(Rx Only\) by the FDA](#) in 2021.

“We’re very pleased with the FDA’s decision,” said Keith Smith, CEO of Vonco Products. “EnteraLoc Flow is designed to improve the nutrition of enteral patients by providing a convenient method of food delivery that is simple, safe, reduces mess, and can be consumed on the go. Designating EnteraLoc Flow as an OTC solution will help physicians and caregivers deliver better enteral care.”

To earn the OTC designation, Vonco offered Human Factors study data that overwhelmingly demonstrated that the EnteraLoc Flow feeding system is safe and effective and that the instructions were clear enough to facilitate proper use by the average person.

“Proper nutrition can be lifesaving to enteral patients,” said David Marks, President and CEO of Medtrition, an international supplier of medical foods. “Being able to administer enteral nutrition quickly and safely with just a squeeze of a pouch equipped with the EnteraLoc Flow direct-connect ENFit® device reinvents enteral tube feeding. As a valued partner of Vonco, we look forward to expanding our enteral offering to include the EnteraLoc Flow OTC feeding system. When combined with nutritious formulations, I believe there is no better feeding solution for the home enteral community.”

EnteraLoc Flow is a contract manufactured solution sold by brand owners direct to hospitals, health systems, and home care patients. The company estimates the OTC version will be available via online retail by late 2023. In the meantime, the product will remain in readily available supply through current access channels.

To learn more, *visit* the [EnteraLoc website](http://www.enteraloc.com), *call* 800.323.9077, or *email* [sales@vonco.com](mailto:sales@vonco.com).

Vonco is an FDA-registered facility with Class II medical device capability and is ISO 13485:2016 Certified.

### **About EnteraLoc Flow**

EnteraLoc Flow is a patented, 510(k) FDA-cleared, medical fluid device intended for tube-fed patients. It is the first seamless, closed-loop solution combining nutritious meals with a flexible pouch, a leak-proof seal, a custom-designed spout, and a direct-connect ENFit® device in one complete enteral feeding system. Unlike traditional solutions, EnteraLoc Flow uniquely delivers nutrition directly into the patient's feeding tube in either the clinical or home care setting. It is designed to improve the nutrition and hydration of tube-fed patients by providing a method of nutrient delivery that is convenient, simple, safe, mess-free, and can be consumed on the go.

### **About Vonco**

Vonco Products ([www.vonco.com](http://www.vonco.com)) delivers the experience, innovation, technology, and creativity needed to take ideas from concept to commercialization – as quickly as possible. Both a packaging company and a components company, Vonco fills a unique space of manufacturing both custom flexible packaging solutions and custom flexible component solutions. Vonco started as a custom equipment and packaging pioneer. Now with over sixty years of experience, equipment requests have shifted to designing and manufacturing customized plastic products, packaging, and components. The unparalleled ability to customize liquid tight bags of any desired shape or fitment using both supported and unsupported films gives Vonco an edge over peers in medical and consumer markets.

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