Effective: April 19, 2022

Vonco 510(k) Brand Owner Guidance

EnteraLoc™ Flow and EnteraLoc™ Pump

(for ENFit® and EN+ direct connections)

Award-winning 510(k) enteral device that sets the bar for future direct connect delivery of nutrition – blended and non-blended.

EnteraLoc™ Flow is a patent-pending, FDA 510(k) approved, medical fluid device intended for tube fed patients. This is the first seamless, closed-loop solution that combines nutritious meals with a flexible pouch, leak-proof seal, custom-designed spout, and direct-connect ENFit® device in one complete enteral feeding system. Unlike traditional solutions, EnteraLoc uniquely delivers nutrition directly into the patient's feeding tube in either the hospital, long term care facility, rehab facility or home care setting. It's designed to improve the nutrition/hydration of tube fed patients by providing a convenient method of nutrient delivery that is simple, safe, less mess, and can be consumed on-the-go. Vonco is in the process of obtaining a 510(k) clearance for EnteraLoc Pump, an EN+ direct connection system.

EnteraLoc is a contract manufactured medical device sold by brand owners (using their liquid or blenderized formula) direct to hospitals, health systems and home care patients. As such, the FDA considers this a Class II 510(k) medical device that must comply with applicable regulatory requirements.

Although Brand Owners are ultimately responsible for compliance with applicable FDA regulations, Vonco has removed the burden of required design, development, manufacturing and reporting regulatory requirements. We guide you along the way and make it easier for Brand Owners to comply with all applicable FDA regulations.

Guidance for this approach is based on our consultation with the FDA:

- Vonco files the 510(k) with the FDA
- With its FDA compliant Quality System, Vonco is designated as your supplier and agrees to hold the Design History File documents and records
- Brand Owners register and list with the FDA as "Specification Developer" and "Complaint File Establishment"
- Brand Owners will be responsible for applicable Quality System Regulations including Complaint Handling, Management Controls and Purchasing Controls. Vonco can provide assistance with compliance requirements.

Brand Owners should review with the FDA, or with a consultant, individual compliance requirements. If you have any questions about how the Vonco 510(k) EnteraLoc Flow and EnteraLoc Pump product strategy can make the FDA filing and compliance process easier, contact your account manager. Guidance is subject to change.

10826 250th Avenue
Trevor, Wisconsin 53179
800-323-9077
sales@vonco.com

Vonco 510(k) FAQ

EnteraLoc™ Flow and EnteraLoc™ Pump

(for ENFit® and EN+ direct connections)

How does the FDA define a specification developer?
The FDA defines a Specification Developer as someone who develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing. This includes establishments that, in addition to developing specifications, also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

When is a brand owner the specification developer?
Vonco Products owns the product design and maintains a full DHF file. The labeling on the pouch, however, is specific to the Brand Owner and not owned by Vonco. Since labeling specifications are owned by the Brand Owner, we recommend that the Brand Owner registers as the specification developer.

What guidance do you have for medical devices that are private labeled?
According to the FDA Center for Devices and Radiological Health (CDRH): There is a narrow type of "private label company" that are sometimes referred to as an "own name labeler." That would be a facility that performs no function other than to affix a label with their own brand name. It is current policy that if that facility does not perform any other functions, and the changes to the labeling do not change or cover up any substantive content, the FDA will exert regulatory discretion and have no specific regulatory expectations of that facility unless they become aware of a risk to public health.

However, if the private labeler is handling complaints they will be expected to register and list and have a quality system that is capable of at least properly handling those complaints. If they only collect the complaints and forward them on to the original manufacturer, they will still need a system that includes procedures for that function.

If they are changing the device in any way or making labeling changes that affect content beyond the brand name information, they would be considered a finished device manufacturer. If they are requesting "minor" changes that are realized by the original manufacturer, then they would be considered a specification developer. In either instance, they would be expected to conform to all applicable regulatory requirements.

10826 250th Avenue
Trevor, Wisconsin 53179
800-323-9077
sales@vonco.com

Does Vonco currently have 510(k) clearance for the EnteraLoc Flow product?
Vonco is pleased to announce that the EnteraLoc™ Flow direct-connect enteral nutritional delivery system was granted 510(k) clearance by the United States' Food and Drug Administration in August 2021. For more details, refer here to the official press release. Current approval is for a prescription product with a planned OTC submission.

Does Vonco currently have 510(k) clearance for the EnteraLoc Pump product?
Vonco is currently working to obtain EnteraLoc Pump clearance, but is still in process.

Once cleared, will Vonco list the product under their establishment registration as a manufacturer?
Vonco Products obtained 510(k) clearance and has listed the device appropriately. Proprietary names were added to the listing which will support variations in design and labeling.

Who is responsible for obtaining and applying the UDI labeling?
The Brand Owner is responsible for obtaining and applying the UDI labeling. The FDA CDRH UDI Help Desk Team, has provided the following information:

21 CFR 801.3 defines "labeler" as (1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and (2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler. The labeler for UDI purposes is the firm whose information appears on the label to satisfy the requirements under 21 CFR 801 (including brand or trade name, contact name, and contact information).

10826 250th Avenue
Trevor, Wisconsin 53179
800-323-9077
sales@vonco.com

Vonco 510(k) Product Labeling

EnteraLoc™ Flow and EnteraLoc™ Pump

(for ENFit® and EN+ direct connections)

Proposed EnteraLoc Labeling

Vonco Products has created proposed instructions for use for the EnteraLoc product family. These Instructions for Use (IFU's) will be provided to the FDA for 510K submission purposes. Brand Owners may use these documents for a guide to complete any necessary IFU's that will be included in product packaging.

While there are no specific requirements for items that must be included in the instruction for use or product labeling/artwork, Vonco Products suggests that the following be included on any product labeling/artwork:

1. Pouch must be in upright position when connected to male ENFit connector
2. Not for IV use
3. Single patient use
4. Do not use if damaged or open
5. The EnteraLoc pouch with enteral specific spout incorporates a connector which is designed to reduce the likelihood of tubing misconnections; however, the potential to misconnect this device with connectors of other healthcare applications still exist.
6. If marketing as an Rx
    a. IFU must bear the Rx only symbol
    b. Product labeling must state: Use under medical supervision

ISO 15223:2016 (Symbols to be used for medical device labels, labelling, and information to be supplied) contains a listing of symbols and their specific meanings, which can be used on medical device labeling. The use of symbols is not required. The symbols in ISO 15223:2016 can be utilized in place of wording when a symbol is available.

10826 250th Avenue
Trevor, Wisconsin 53179
800-323-9077
sales@vonco.com