



Food and Drug Administration  
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August 17, 2017

U Deliver Medical, LLC  
% Roger Gray  
VP, Quality And Regulatory  
Donawa Lifescience Consulting S.r.l.  
Piazza Albania, 10  
Rome, 00153  
Italy

Re: K170555  
Trade/Device Name: U Deliver Bolink ENFit Enteral Feeding Sets  
Regulation Number: 21 CFR§ 876.5980  
Regulation Name: Gastrointestinal Tube and Accessories  
Regulatory Class: II  
Product Code: PIF  
Dated: July 11, 2017  
Received: July 14, 2017

Dear Roger Gray:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

  
Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K170555

Device Name

U Deliver Bolink ENFit Enteral Feeding Sets

Indications for Use (Describe)

The U Deliver Bolink ENFit Enteral Feeding Sets are intended to deliver liquid nutritional formulas or water to a patient's enteral access device (feeding tube).

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

**Trade Name:** U Deliver Bolink ENFit Enteral Feeding Sets

**Type of 510(k) submission:** Traditional

**Date of Submission:** 16 August 2017

**Manufacturer:** Cedic S.r.l.  
Biomedical Division  
Via Liberazione, 63/9  
20068 Peschiera Borromeo (MI)  
Italy

**510(k) Owner and Submitter:** U Deliver Medical, LLC  
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Woodbury, MN 55129  
USA

**Phone:** 612-381-7330

**FDA Registration Number:** Not yet registered

**Owner/Operator Number:** Not yet registered

**510(k) Application Correspondent:** Mr Roger Gray  
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**FDA Product Code:** PIF

**FDA Regulation Number:** 876.5980

**FDA Classification Name:** Gastrointestinal tubes with enteral specific connectors

**Classification Panel:** Gastroenterology and Urology

**Common Name:** Enteral Feeding Sets

**FDA Classification:** Class II

**FDA Identification:** The connector is attached to an enteral tube and is intended to facilitate the administration of hydration, medication, and feed to a patient.

### Device Description:

The U Deliver Bolink ENFit Enteral Feeding Sets consist of two configurations:

- U Deliver Bolink Small Cap Gravity Feeding Set with Cross Spike and ENFit Connector (ref. BK-1085)
- U Deliver Bolink Large Cap Gravity Feeding Set with ENFit Connector (ref: BK-1405)

The U Deliver Bolink Small Cap Gravity Feeding Set with Cross Spike and ENFit Connector uses the free flow of gravity to dispense enteral feeding solutions from a distal reservoir (not supplied) which connects via a safety screw connection meeting the requirements of clauses 4 “General requirement” and 5 “Dimensional requirements for enteral feed reservoir connectors” of ISO/DIS 18250-3, ‘Connectors for reservoir delivery systems for healthcare applications - Part 3: Enteral applications’, to a PVC tube with external clamp, to a distal ENFit connector, meeting the requirements of ISO 80369-3, ‘Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications’.

The U Deliver Bolink Large Cap Gravity Feeding Set with ENFit Connector uses the free flow of gravity to dispense enteral feeding solutions from a distal reservoir (not supplied) which connects via a screw cap with a 40 mm thread, to a PVC tube with external clamp, to a distal ENFit connector, meeting the requirements of ISO 80369-3

Both sets are constructed from medical grade, biocompatible materials, and are supplied non-sterile for single patient use only.

### **Indications for Use/Intended Use**

The U Deliver Bolink ENFit Enteral Feeding Sets are intended to deliver liquid nutritional formulas or water to a patient’s enteral access device (feeding tube).

### **Principle of operation, mechanism of action, and interaction with the patient**

The U Deliver Bolink ENFit Enteral Feeding Sets operate by providing a means of interconnecting enteral feeding solution reservoirs to a patient’s enteral access device (feeding tube), so that patient enteral feeding can take place when ‘new generation’ enteral end fittings in accordance with ISO 80369-3 (‘ENFit’ connections) are present on the feeding tube. A clamp is provided on the tubes to allow feeding to be turned on or off. Although contact of components of the Enteral Feeding Sets may accidentally occur with patient’s intact skin during use, the Enteral Feeding Sets have a central fluid path through which feeding solutions flow into the patient during the feeding process.

The U Deliver Bolink ENFit Enteral Feeding Sets are intended for prescription use only.

U Deliver Bolink ENFit Enteral Feeding Sets are not intended for a specific patient population: they can be used for adults, children, infants and neonates.

### **Device Specification**

The ENFit connectors on the Enteral Feeding Sets are designed in compliance with FDA-recognized standard ISO 80369-3 “Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications”, and tested in accordance with FDA-recognized standard ISO 80369-20 “Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods”.

The safety screw connector on the U Bolink ENFit Deliver Enteral Set with Safety Screw Connector is designed in accordance with ISO/DIS 18250-3.

The screw cap on the U Deliver Bolink Large Cap Gravity Feeding Set with ENFit Connector is designed with identical major dimensions to the identified predicate device, Metrixcare model 70040, Gravity Set with Feeding Cap (K132424).

### **Manufacture**

The U Deliver Bolink ENFit Enteral Feeding Sets are assembled from components manufactured by subcontractors/suppliers to Cedic, the contract manufacturer, in environmentally controlled areas (clean room Class 8 according to ISO 14644), together with tubing and adhesive sourced ‘off-the-shelf’ by Cedic from other suppliers.

## Performance Data

Bench tests have been carried out on samples of the U Deliver Bolink ENFit Enteral Feeding Sets, including:

- Fluid leakage
- Stress cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding
- Disconnection by unscrewing
- Dimensional analysis of ENFit connectors
- Biocompatibility testing according to ISO 10993
- Flow rate testing using water and enteral feeding formula
- Tensile testing
- Packaging validation

## Predicate device

The Predicate Device selected for comparison with the U Deliver Bolink ENFit Enteral Feeding Sets:

Predicate Device:	Metrixcare Enteral Feeding Sets
Sponsor:	The Metrix Company, USA
510(k) Number:	K132424
Clearance Date:	12 February 2014
FDA Product Code:	KNT
Classification Name:	Gastrointestinal tubes and accessories
Regulation No:	876.5980

The Subject Device and the Predicate Device have many identical properties and features. The only differences that exist are:

The components included within the enteral feeding sets are different. The predicate includes a sight chamber, while the subject device does not, and the predicate includes a roller clamp, whereas the subject device includes an on/off clamp. These differences do not have any significant effect on the safety or effectiveness of the subject device.

The predicate device that uses the large screw cap at the proximal end has a minimum lumen diameter of 3.4 mm, whereas the equivalent subject device has a minimum lumen diameter of 4.0 mm. This difference allows a faster feeding rate for the subject device, but does not have any significant effect on the safety or effectiveness of the subject device.

The predicate device has a vented feeding cap, whereas the subject device cap is non-vented. The venting on the predicate device allows use of the predicate feeding set with both flexible and rigid feeding containers, while the subject device feeding set can be used only with flexible feeding containers. The subject device labeling includes a warning not to use with rigid containers.

## Conclusion:

Based on the information contained within this submission, it is concluded that the U Deliver Bolink ENFit Enteral Feeding Sets are substantially equivalent to the identified sets within the predicate device that are already in interstate commerce within the USA.