



Food and Drug Administration  
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February 9, 2016

Vygon  
Jillian Mikovich  
Regulatory Affairs Manager  
2750 Morris Road, Suite A200  
Lansdale, PA 19446

Re: K151237  
Trade/Device Name: Nutrisafe 2 - ENFit Adaptor  
Regulation Number: 21 CFR§ 876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: PIO  
Dated: January 4, 2016  
Received: January 7, 2016

Dear Jillian Mikovich,

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 yours,

**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)

K151237

Device Name

Nutrisafe 2 – ENFit Adaptor

Indications for Use (Describe)

The Nutrisafe 2 – ENFit adaptor is indicated for enteral use only. It enables the connection between an administration set equipped with a female ENFit connector at its distal end and a Nutrisafe 2 feeding tube equipped with a male Nutrisafe 2 connector at its proximal end.

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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**PREMARKET NOTIFICATION**  
**510(k) SUMMARY**  
**(As Required By 21 CFR §807.92)**

**510k number:** K151237

**Applicant:** Vygon  
2750 Morris Road, Suite A200  
Lansdale, PA 19446

**Contact Name:** Jillian Mikovich  
Manager, Regulatory Affairs  
Phone: 800-473-5414  
Fax: 215-672-6740

**Trade Name:** Nutrisafe 2 – ENFit Adaptor  
**Common Name:** Enteral Specific Transition Connector  
**Regulation Number:** 876.5980  
**Product Code:** PIO  
**Classification Name:** Enteral Specific Transition Connector, 21 CFR §876.5980  
**Regulatory Class:** Class II  
**Predicate Device:** Cedic Enteral Distal End Transition Connector, K140581  
**Date Prepared:** May 7, 2015

**Device Description:**

The Nutrisafe 2 – ENFit adaptor is indicated for enteral use only. It enables the connection between an administration set equipped with a female ENFit connector at its distal end and a Nutrisafe 2 feeding tube equipped with a male Nutrisafe 2 connector at its proximal end. Vygon has not previously submitted any 510(k)s for the subject device.

**Intended Use:**

The Nutrisafe 2 – ENFit adaptor is indicated for enteral use only. It enables the connection between an administration set equipped with a female ENFit connector at its distal end and a Nutrisafe 2 feeding tube equipped with a male Nutrisafe 2 connector at its proximal end.

**Technology Characteristics:**

The subject device allows for connection to the Nutrisafe 2 feeding system while the predicate device will allow connection to a funnel connector. The difference in technological characteristics does not diminish the substantial equivalence to the predicate device.

**Non-Clinical Summary:**

Non-clinical verification of Nutrisafe 2 – ENFit Adaptor was conducted through bench testing. Testing confirmed physical attributes and device performance meet the requirements of standards performance and biocompatibility. Nutrisafe 2 – ENFit Adaptor passed biocompatibility testing including cytotoxicity, sensitization and intracutaneous injection,

performed in accordance with ISO 10993. Testing also confirmed device performance meets the requirements including dimensional analysis, fluid leakage, stress cracking, resistance to separation from axial load and unscrewing, resistance to overriding, disconnection by unscrewing, flow testing and misconnection risk analysis. Results of this testing indicate that the Nutrisafe 2 – ENFit Adaptor meets all specifications and intended use.

**Conclusion:**

Given the testing mentioned above, the subject device, Nutrisafe 2 – ENFit Adaptor is as safe, as effective and performs as well as the legally marketed predicate device, Cedic Enteral Distal End Transition Connector.