510K Summary

SEP 15 2006

Date of Preparation: March 28, 2006

Applicant: Vygon Corporation
2495 General Armistead Ave.
Norristown, PA 19403

Contact Individual: Courtney Smith, Regulatory Affairs Manager
610-539-9300 Ext. 110

Trade Name: Nutrisafe 2

Common Name: Feeding tube

Regulation Number: 876.5980

Product Code: FPD

Classification Name: Gastrointestinal tube and accessories devices

Classification: Class II

Predicate Device Name: Nutrisafe (K991918/ K003311), Vygon Enteral Nutrition Tube (K820176)

Device Description: The Nutrisafe 2 is a complete system of feeding tubes and accessories. The feeding tubes are available in several configurations and in three materials: DEHP-free PVC, Polyurethane, and Silicone. A recent report in the FDA Patient Safety News: Show #46, December 2005, discussed the risks associated with health care personnel mistakenly connecting the wrong devices to the wrong luer connection. Often, this kind of error can result in fatal results. One of the benefits of the Nutrisafe 2 is that the connection does not incorporate a luer, and thus eliminating the risk of inadvertently connecting the system to an IV system. The Nutrisafe 2 feeding tube features a locking connection which eliminates the risk of involuntary disconnection; voluntary disconnection is achieved by simply unscrewing the hub connections. Another benefit of the Nutrisafe 2 is that it does not change the technique of the end-user, and therefore it does not require any special training.

The Nutrisafe 2 consists of the following:

Description	Reference
Feeding Tubes	361.xxx, 362.xxx, 363.xxx, 1361.xxx, 1362.xxx, 1363.xxx, 2332.xxx2395.xxx
Syringes and Syringe Accessories	1015.xxx, 818.xxx, 828.xxx
Accessories	368.xxx, 5802.xx
Sampling Devices	821.xxx, 817.xxx

Intended Use: For nasogastric/oralgastric enteral feeding, incorporating safety connectors which eliminates the risk of IV administration through the feeding tube

Technology Characteristics: The Nutrisafe 2 feeding tubes are available in several configurations and in three materials: DEHP-free PVC, Polyurethane, and Silicone. Additional the feeding system contains a unique connection does not incorporate a luer. The locking connection eliminates the risk of involuntary disconnection; voluntary disconnection is achieved by simply unscrewing the hub connections.

Summary of Design Control Activities:
Biocompatibility testing of the material demonstrates that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The only changes between the predicate device (Nutrisafe K003311 / K991918) and the Nutrisafe 2 is the use of DEHP-free PVC and the unique non-luer connection. The only difference between the predicate device (Enteral Nutrition Tube K820176) is the additional sizes and the unique non-luer connection. Biocompatibility testing, performance testing and risk assessment demonstrate that the Nutrisafe 2 meets manufacturers specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Courtney Smith
Regulatory Affairs Manager
Vygon Corporation
2495 General Armistead Avenue
NORRISTOWN PA 19403

SEP 15 2006

Re: K060944
Trade/Device Name: Nutrisafe 2
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Dated: September 8, 2006
Received: September 8, 2006

Dear Ms. Smith:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060944

Device Name: Nutrisafe 2

Indications For Use:

For nasogastric/oralgastric enteral feeding, incorporating safety connectors which eliminates the risk of IV administration through the feeding tube.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060944