December 19, 2024

Vygon USA
Chris Steinke
Quality Assurance and Regulatory Affairs Manager
2750 Morris Road Suite A200
Lansdale, Pennsylvania 19446

Re: K243361
Trade/Device Name: Nutrifit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: FPD, KNT
Dated: October 29, 2024
Received: October 29, 2024

Dear Chris Steinke:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anthony Lee -S

Anthony Lee, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243361

Device Name

Nutrifit

Indications for Use *(Describe)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 2024-10-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vygon USA
Applicant Address	2750 Morris Road Suite A200 Lansdale PA 19446 United States
Applicant Contact Telephone	603-743-5988
Applicant Contact	Mr. Chris Steinke
Applicant Contact Email	csteinke@vygon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Nutrifit
Common Name	Gastrointestinal tube and accessories
Classification Name	Tube, Feeding
Regulation Number	876.5980
Product Code(s)	FPD, KNT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K060944	Nutrisafe 2	FPD

Device Description Summary

21 CFR 807.92(a)(4)

Nutrifit is a combined system of feeding tubes and extension sets. The feeding tubes are available in several configurations: Not made with DEHP PVC and Polyurethane (PUR). The PUR versions are available without stylet. All tubes include centimeter numerical markings from 5 to 35 cm for the 40, 50 and 75 cm feeding tubes and markings from 5 to 70 cm for the 90, 125 and 160 cm feeding tubes.

The Nutrifit devices are single-use, disposable devices intended for use for enteral nutrition in adults and children. Nutrifit PVC feeding tubes are intended for enteral nutrition and for a short-term use, not longer than 5 days. Nutrifit PUR feeding tubes are intended for enteral nutrition and for a short-term use, not longer than 29 days.

The Nutrifit accessories for this submission are extension sets, which enable longer connections for the feeding tubes. They allow greater freedom of movement and greater flexibility and are available with or without a pinch clamp.

Nutrifit is ENFit compliant, meeting requirements for design and functional performance of small-bore connectors intended to be used for connections on enteral medical devices and accessories as detailed in ISO 80369-3.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same in both the subject device and the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Nutrifit and the predicate device (Nutrisafe 2) share similar technological characteristics. Both devices contain similar components including PVC feeding tubes, PUR feeding tubes, extension line sets, and accessory components. The inclusion of additional lengths of the feeding tubes and extension sets in the proposed Nutrifit system along with y-connector does not raise any new issue of safety and efficacy. A risk management file in compliance with EN ISO 14971:2019, Medical Devices; Application of Risk Management to Medical Devices was completed to assess the impact of the additional lengths and catheter sizes of the feeding tubes and extension sets. Adequate non-clinical performance bench testing was conducted to mitigate risk where possible as part of the design control activities. All tests pertaining to the Nutrifit met their respective acceptance criteria. Per the risk assessment, the Nutrifit does not introduce any new issue of safety and efficacy.
Packaging validation studies were conducted and the tests results demonstrate that the sterile barrier system of the device package can maintain its strength, integrity, and microbial barrier until the end of the intended shelf life.
Although there are slight differences in the design features of the proposed device and the predicate device, these differences were found to be insignificant overall, and the principle of operation remains the same. The Vygon Nutrifit device is considered substantially equivalent to the predicate device in technological characteristics (design and materials) based on the above evaluation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Bench Testing was conducted in order to support this submission. To ensure that the proposed device design and construction are suitable for the intended use and is substantially equivalent, the Nutrifit device has been evaluated in the following tests:
Performance Bench Testing has been conducted to verify that the performance of the proposed Nutrifit device is substantially equivalent to the predicate device, and the Nutrifit device will perform as intended. The following bench-top testing were conducted to assure conformance to the specifications in accordance with ISO 80369-3:
a. Resistance to separation from unscrewing,
b. Resistance to overriding
c. Disconnection by unscrewing,
d. Fluid leakage at a pressure of 3.2 bar for 30 seconds,
e. Stress cracking,
f. Resistance to separation from axial load.
Flow rate testing was conducted on Nutrifit and predicate device Nutrisafe 2 according to FDA cited protocol “Gravity Flow Rate Testing in Enteral Tube" https://cdrh-rst.fda.gov/gravity-flow-rate-testing-enteral-tube

The VYGON's Nutrifit device met all predetermined acceptance criteria as specified by the applicable standards, FDA guidance documents and internal test protocols. No safety and efficacy issues were raised during the testing program. Therefore, the Nutrifit device is considered substantially equivalent to the predicate device.
The safety and effectiveness of the Nutrifit device are adequately supported by the non-clinical performance data, substantial equivalence information, materials information, and comparison of design characteristics provided within this premarket notification.