February 28, 2022

Pentaferte Italia S.R.L.
% Stephanie Rose
Regulatory Affairs Manager
Vygon USA
2750 Morris Rd Suite A200
Lansdale, PA 19446

Re: K211661
Trade/Device Name: ENFit enteral syringes (NUTRIFIT)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: January 26, 2022
Received: January 28, 2022

Dear Lauren Doyle:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Shanil P. Haugen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211661

Device Name
ENFit enteral syringes (NUTRIFIT)

Indications for Use *(Describe)*
Nutrifit™ Single Use /Enteral Syringes with ENFit Connector (including low dose tip (LDT) versions):

ENFit Nutrifit™ enteral syringes deliver enteral fluids to the gastrointestinal system of a patient who is physically unable to eat and swallow.
The syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician), to clinicians to administer enteral fluids.
ENFit Nutrifit™ enteral syringes are single use devices.
ENFit Nutrifit™ enteral syringes are intended for pediatric and adult use.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4 510(k) SUMMARY, AS REQUIRED BY 21 CFR 807.92

Submitter's Name Address	Pentaferte Italia S.r.l. Viale Piane Nocella, 23, I-64012 Campli (TE) - Italy
Establishment Registration Number	3004756837
Summary Preparation Date	January 26, 2022
Contact Person Telephone Number Fax Number	Stephanie Rose 1(603)403-0809 1(215)672-6740
Name of Device	ENFit enteral syringes NUTRIFIT™
Common name of Device	ENFit enteral syringes
Classification Name and Class	Gastrointestinal tube and accessories Device Class: II Product Code: PNR Regulation Number 21 CFR 876.5980
Performance Standards	ISO 80369-3:2016 - Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications ISO 7886-1:2018 - Sterile hypodermic syringes for single use ISO 7886-2:2020 "Sterile hypodermic syringes for single use – Syringes for use with power driven syringes" ISO 80369-20:2015 - Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test reports ISO 11135: 2014 - Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices. ISO 11737-1:2018 - Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products ISO 14971:2020 - Medical devices - Applications of risk management to medical devices ISO 15223-1:2016 - Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements ISO 11607-1:2019 - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems ISO 11607-2:2019 - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes ASTM F1980: 2016 - Standard guide for accelerated aging of sterile medical device packages ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5:

<table>
<tr><td></td><td>Tests for in vitro cytotoxicity
ISO 10993-10:2013 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization</td></tr>
<tr><td>Description of Device</td><td>ENFit enteral syringes are designed to reduce the accidental risk of connection to a parenteral system, as required by ISO 80369-3:2016, allowing only enteral use. The syringes are available in single use configurations.

An enteral syringe consists of a syringe barrel with integral tip (ENFit), plunger, gasket, barrel lubricant and can be supplied with or without a syringe tip cap.

Only the 5mL single use syringe can be connected with compatible enteral syringe-driver pumps; the other syringes are for manual use.</td></tr>
<tr><td>Indications for Use</td><td><u>Nutrifit™ Single Use /Enteral Syringes with ENFit Connector (including low dose tip (LDT) versions):</u>

ENFit Nutrifit™ enteral syringes deliver enteral fluids to the gastrointestinal system of a patient who is physically unable to eat and swallow.
The syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician), to clinicians to administer enteral fluids.
ENFit Nutrifit™ enteral syringes are single use devices.
ENFit Nutrifit™ enteral syringes are intended for pediatric and adult use.</td></tr>
<tr><td>Identification of Predicate Device</td><td>The following predicate devices have been identified:

<u>Predicate Device:</u>
<table>
<tr><td>Device Classification Name:</td><td>Enteral Syringes With Enteral Specific Connectors</td></tr>
<tr><td>510K Number:</td><td>K161141</td></tr>
<tr><td>Trade/Device Name:</td><td>ENFit enteral pump syringes PENTA ™
ENFit enteral pump syringes NUTRIFIT™</td></tr>
<tr><td>Regulation Number:</td><td>21 CFR 876.5980</td></tr>
<tr><td>Regulation Name:</td><td>Gastrointestinal Tube and Accessories</td></tr>
<tr><td>Regulatory Class:</td><td>II</td></tr>
<tr><td>Product Code:</td><td>PNR</td></tr>
<tr><td>Applicant:</td><td>PENTAFERTE ITALIA S.R.L.
VIALE PIANE NOCELLA, 23
Campli, ITI-64012</td></tr>
</table></td></tr>
<tr><td>Performance Summary</td><td>In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between ENFit enteral syringes NUTRIFIT ™, and predicate device.

The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to</td></tr>
</table>

	the requirements for its intended use and performs comparably to the existing predicate device. In vitro bench tests were carried out, according to the requirements of FDAs document Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s and applicable standards. The following areas have been tested and/or evaluated: Performance test according to ISO 7886-1/-2 & ISO 80369-3/-20 including testing after simulated clinical use and cleaning Biocompatibility tests according to ISO 10993 series requirements Sterility validation and tests according to ISO 11135 Packaging validation and tests according to ISO 11607-1/-2 Labelling requirements according to ISO 15223-1 and FDA Guidance "Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications" Results from these evaluations demonstrated that the ENFit enteral syringes **NUTRIFIT ™** are safe and effective to meet their intended use.
Substantial Equivalence	ENFit enteral syringes NUTRIFIT ™ are similar to the predicate device in terms of intended use, indications for use, and medical technique. Based on the safety and performance testing, technological characteristics, and the indications for use for the device, the proposed ENFit enteral syringes **NUTRIFIT**™, have been demonstrated to be appropriate for its intended use and is considered substantially equivalent to the ENFit Enteral Pump Syringes PENTA ENFit/ENFit Enteral Pump Syringes NUTRIFIT (K161141).

Table 3 – Summary Table