DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 22, 2017

Pentaferte Italia S.r.l.
Rosa Di Gioia
Regulatory Affairs Manager
Loc. Nocella S.P. 262
I-64012 Campli (TE)
Italy

Re: K161141
Trade/Device Name: ENFit enteral pump syringes PENTA ENFit™
ENFit enteral pump syringes NUTRIFIT™
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: January 9, 2017
Received: February 1, 2017

Dear Rosa Di Gioia:

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,

Joyce M. Whang -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161141

Device Name
ENFit enteral pump syringes PENTA ENFit TM
ENFit enteral pump syringes NUTRIFIT TM

Indications for Use *(Describe)*

ENFit enteral pump syringes PENTA ENFit TM and ENFit enteral pump syringes NUTRIFIT TM deliver nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. ENFit enteral pump syringes (PENTA ENFit TM and NUTRIFIT TM) are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to health care professionals, to administer nutritional formula. In particular, these syringes can be connected with enteral infusion pump.
ENFit enteral pump syringes (PENTA ENFit TM and NUTRIFIT TM) are intended for neonatal, pediatric and adult use.
ENFit enteral pump syringes are single use devices.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Traditional 510(k)
K161141
510(K) Summary
ENFit enteral pump syringes
Rev.06 – Mrch 16th 2017

510(K) SUMMARY, AS REQUIRED BY 21 CFR 807.92

Submitter's Name **Address**	Pentaferte Italia s.r.l. Loc. Nocella SP 262, I-64012 Campli (TE) – Italy
Summary Preparation Date	January 09th, 2017
Contact Person **Telephone Number** **Fax Number**	Dr. Rosa Di Gioia, Regulatory Affairs Manager +39.0861.560201 +39.0861.560200
ENFit Syringes to be connected with enteral infusion pump (ENFit enteral pump syringes)	
Name of the Device	ENFit enteral pump syringes **PENTA ENFit ™** ENFit enteral pump syringes **NUTRIFIT ™**
Common name of the device	ENFit enteral pump syringes
Classification Name and class	Enteral syringes with enteral specific connectors Device Class: II Product Code: PNR Regulation Number 21 CFR 876.5980
Performance Standards	– ISO 803693-3:2016 Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications – AAMI/ANSI/ISO 80369-1:2010 - Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements – AAMI/CN3:2014 (PS) Small Bore Connectors For Liquids And Gases In Healthcare Applications Part 3: Connectors For Enteral Applications – EN ISO 7886-1:1997: Sterile hypodermic syringes for single use. Syringes for manual use – EN ISO 7886-2:1997. Sterile hypodermic syringes for single use. Syringes for use with power-driven syringe pumps – ANSI/AAMI/ISO 80369-20:2015, Smallbore connectors for liquids and gases in healthcare applications – Part 20: Common test methods – EP § 3.2.8 – ASTM D790- 15e2 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials – EN 1615:2000 - Enteral Feeding Catheters And Enteral Giving Sets For Single Use And Their Connectors Design And Testing – AAMI ANSI ID54:1996/(R)2012 Enteral Feeding Set Adapters And

Traditional 510(k)
K161141
510(K) Summary
ENFit enteral pump syringes
Rev.06 – Mrch 16th 2017

	Connectors
DESCRIPTION of the device:	ENFit enteral pump syringes are designed to reduce the accidental risk of connection to a parenteral system, as required by AAMI/CN3:2014 (PS), allowing only enteral use. In particular, these high volume syringes (sizes 10ml, 20 ml and 60ml) can be connected with enteral infusion pump. They have plungers, made of synthetic rubber which does not contain natural latex, in order to prevent any allergies.
Indications for Use	ENFit enteral pump syringes **PENTA ENFit ™** and ENFit enteral pump syringes **NUTRIFIT ™** deliver nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. ENFit enteral pump syringes **(PENTA ENFit ™** and **NUTRIFIT ™**) are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to health care professionals, to administer nutritional formula. In particular, these syringes can be connected with enteral infusion pump. ENFit enteral pump syringes **(PENTA ENFit ™** and **NUTRIFIT ™**) are intended for neonatal, pediatric and adult use. ENFit enteral pump syringes are single use devices.
Identification of Predicate Device	Proprietary Name: NeoMed, Inc - K143344 Classification Name: Gastrointestinal tube and accessories devices; 21 CFR 876.5980 - K122373 Classification Name: Piston Syringe; 21 CFR 880.5560 Registered Establishment Name: NeoMed, Inc Registered Establishment Number: 3006520777 Owner/Operator: NeoMed, Inc. Owner/Operator Number: 10022926 Manufacturer 510 (k): K143344 Device Name: NeoConnectTM Enteral Syringes Manufacturer 510 (k): K122373 Device Name: NeoMed Oral / Enteral Syringe Applicant: NeoMed, Inc. 100 Londonderry Court Suite 112 Woodstock, GA 30188

Traditional 510(k)
K161141
510(K) Summary
ENFit enteral pump syringes
Rev.06 – Mrch 16th 2017

Common name of the predicate device for principles of operations	– K143344 NeoConnect™ Enteral Syringes – K122373 NeoMed Oral / Enteral Syringe
Classification Name of the device	– K143344 Gastrointestinal tube and accessories devices Device Class: II Product Code: PIF Regulation Number: 21 CFR 876.5980 – K122373 Piston Syringe Device Class: II Product Code: FMF Regulation Number: 21 CFR 880.5560
Applicant name and address:	NeoMed, Inc. 100 Londonderry Court Suite 112 Woodstock, GA 30188
Comparison of Technological Characteristics	In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between ENFit enteral pump syringes **PENTA ENFit ™** , ENFit enteral pump syringes **NUTRIFIT ™** , and predicate devices. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing predicate devices.

	Predicate device: NeoMed NeoConnect™ Enteral Syringes with ENFit Connector (K143344)	**Predicate device: NeoMed Oral / Enteral Syringe (K122373)**	**Subject Device** ENFit enteral pump syringes **PENTA ENFit™**, ENFit enteral pump syringes **NUTRIFIT ™ (K161141)**	**Comparison Description/ Justification for the differences**
Device description	An enteral syringe consisting of a syringe barrel with integral tip (ENFit), plunger, gasket, barrel lubricant and supplied with a syringe tip cap.	An oral / enteral syringe consisting of a syringe barrel with integral tip (tapered), plunger, gasket, barrel lubricant and supplied with a syringe tip cap.	ENFit enteral pump syringes consists of disposable enteral feeding syringes that deliver nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. ENFit enteral pump	No relevant difference. No reference to the ENFit connector in K122373 is due to the absence of specific standards requirements at time of that submission.

			syringes are designed so that, while administering enteral solutes and medication, any accidental risk of connection to a parenteral system is prevented, through the female ENFit connector for connection to an enteral access device, designed according to the AAMI/CN3:2014 (PS) Part 3 requirements, allowing only enteral use.	
Indication for Use	The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.	The device is indicated for use as a dispenser, a measuring device and an oral fluid transfer device. It is used to inject fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.	ENFit enteral pump syringes **PENTA ENFit ™** and ENFit enteral pump syringes **NUTRIFIT ™** deliver nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. ENFit enteral pump syringes **(PENTA ENFit ™** and **NUTRIFIT ™)** are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to health care professionals, to administer nutritional formula. In particular, these syringes can be connected with enteral infusion pump. ENFit enteral pump syringes **(PENTA ENFit ™** and **NUTRIFIT ™)** are intended for neonatal, pediatric and adult use. ENFit enteral pump syringes are single use devices.	Indication for use is equivalent, even if the target population of the subject device is wider. Based on the consideration that the target population of the predicates (neonatal and small pediatric patients) is considered worst case if compared with the target population of the subject device (intended for patients of all age groups), the indication for use of the subject device is considered substantially equivalent to those of the predicates. Additional statements on Directions for use and warning according to FDA Guidance "Safety Considerations to Mitigate the Risks of

				Misconnections with Small-bore Connectors Intended for Enteral Applications". No relevant difference.
Model available	0.5ml to 100ml sizes	0.5ml to 100ml sizes	10ml, 20 ml, 60 ml	No relevant difference, Pentaferte Italia devices are in the range of predicate volume sizes.
Pump compatibility	Not specified, but in 510(k) summary is stated that the device is equivalent to the predicate device (K122373, see related column).	Pump compatibility is demonstrated by the statement in the 510(k) summary (K122373) "the devices meet the applicable requirements of ISO 7886-1 and ISO 7886-2, Sterile hypodermic syringes for single use – part 2: syringes for use with power driven syringe pump".	Pump compatibility is demonstrated by the in vitro bench tests on ENFit enteral pump syringes, which show the compliance with the applicable requirements of the ISO 7886-1 and ISO 7886-2, (see also Chapter 17 and related documents).	No difference, pump compatibility is demonstrated by the statement in the 510(k) summary (K122373) "the devices meet the applicable requirements of ISO 7886-1 and ISO 7886-2, Sterile hypodermic syringes for single use – part 2: syringes for use with power driven syringe pump" and in vitro bench tests on the subject devices, which show the compliance with the applicable requirements of the ISO 7886-1 and ISO 7886-2, (see also Chapter 17 and related documents)
Connection type	ENFit (Dimensional compliance to AAMI/CN3:2014 (PS) Part 3 Table B.2 Female Enteral Small-Bore Connector).	Tapered	ENFit (Dimensional compliance to AAMI/CN3:2014 (PS) Part 3 Table B.2 Female Enteral Small-Bore Connector).	No difference, presence of ENFit connector is according to AAMI/CN3:2014 (PS) Part 3. No reference to the ENFit connector in

				K122373 is due to the absence of specific standards requirements at time of that submission.
Biocompatibility requirements	The devices satisfy the applicable Biocompatibility requirements according to ISO 10993.	The devices satisfy the applicable Biocompatibility requirements according to ISO 10993.	ENFit enteral pump syringes satisfy the applicable Biocompatibility requirements according to ISO 10993.	No difference
Materials	Polypropylene Ink / Colorants Polydimethylsiloxane Silicone	Polypropylene Ink / Colorants Polydimethylsiloxane Silicone	Polypropylene Ink / Colorants Silicone oil (Polydimethylsiloxane) Latex Free, nontoxic synthetic rubber	No relevant differences
Description of the sterilization method	Ethylene Oxide (EO), 10^{-6} SAL	Ethylene Oxide (EO), 10^{-6} SAL	Ethylene Oxide (EO), 10^{-6} SAL	No difference

Performance Testing (non-clinical)	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, AAMI/CN3:2014 (PS), EN 1615 and ISO FDIS 80369/3, ISO 80369-1/-20 - Bioburden tests, - Sterility tests, - Validation of the EtO Sterilization process, at the PENTAFERTE ITALIA S.r.l. site, Loc. Nocella SP 262, I-64012 Campli (TE) – Italy, - Packaging evaluation, - Labelling evaluation, - EtO Residual, according to EN ISO 10993-7, - Biocompatibility, according to ISO 10993 series requirements. - Usability tests according to AAMI/IEC 62366-1:2015. Results from these performance evaluations demonstrated that the ENFit enteral pump syringes **PENTA ENFit ™** and ENFit enteral pump syringes **NUTRIFIT ™** met the acceptance criteria defined in the product specification and performed comparably to the predicate device.
SUBSTANTIAL EQUIVALENCE:	ENFit enteral pump syringes **PENTA ENFit ™** and ENFit enteral pump syringes **NUTRIFIT ™** are equivalent to the predicate device in terms of intended use, indications for use and medical technique. ENFit enteral pump syringes (**PENTA ENFit ™** and **NUTRIFIT ™**) deliver

	nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. They are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to health care professionals, to administer nutritional formula. In particular, these syringes can be connected with enteral infusion pump. ENFit enteral pump syringes (**PENTA ENFit ™** and **NUTRIFIT ™**), are intended for neonatal, pediatric and adult use. ENFit enteral (**PENTA ENFit ™** and **NUTRIFIT ™**) pump syringes are single use devices. Based on the safety and performance testing, technological characteristics and the indications for use for the device, proposed ENFit enteral pump syringes **PENTA ENFit ™** and ENFit enteral pump syringes **NUTRIFIT ™** have been demonstrated to be appropriate for the intended use and considered substantially equivalent to the, NeoConnect™ Enteral Syringes and NeoMed Oral / Enteral Syringe (K143344, K122373).

Table 1 -Summary Table