September 30, 2021

Jiangsu Caina Medical Co., Ltd.
Jianwei Pan
Management Representative
No.23 Huanxi Road, Zhutang Town
Jiangyin, Jiangsu 214415
CHINA

Re: K211593
Trade/Device Name: Enteral Pump Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: August 24, 2021
Received: August 30, 2021

Dear Jianwei Pan:

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,

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211593

Device Name
Enteral Pump Syringe

Indications for Use *(Describe)*
Enteral Pump Syringe delivers nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow.
Enteral Pump Syringe is 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.
Enteral Pump Syringe is intended for neonatal, pediatric and adult use.
Enteral Pump Syringe is single use device.

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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Tab 7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.
The assigned 510(k) Number: __K211593_____

1. Date of Preparation: 05/10/2021

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Enteral Pump Syringe
Common Name: Enteral Feeding Syringe with ENFit Connector
Regulatory Information
Classification Name: Gastrointestinal tube and accessories
Classification: II;
Product Code: PNR
Regulation Number: 21CFR 876.5980
Review Panel: Gastroenterology/Urology;
Indications for Use Statement:
Enteral Pump Syringe delivers nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow.
Enteral Pump Syringe is 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.
Enteral Pump Syringe is intended for neonatal, pediatric and adult use.
Enteral Pump Syringe is single use devices.

Device Description:
The proposed device is modified device of K190502(ENFit Oral/Enteral Syringe,cleared July 2, 2019) according to 21CFR 820.30. The change is a operation mode change from manual use to use with infusion pump.

The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 1ml to 60ml. The ENFit enteral feeding syringe consists of moveable plunger, piston, calibrated hollow barrel and tip cap(not necessary). At the distal end of the barrel is a female connector, designed according to ISO 80369-3 (often referred to as an ENFit connection). The tip is designed to mate only with enteral administration devices and is incompatible with Luer connectors. The device is used to deliver fluids into the body enterally by connected to an enteral access device with male ENFit connector. The syringes (size 6ml to 60ml) incorporate a female Standard ENFit connector; the syringes (size 1ml and 6ml) incorporate a female low dosing ENFit connector.

There are 2 types of ENFit connector: Side connector ENFit syringe and central connector ENFit syringe. The sizes of the Side connector ENFit syringe range from 12ml to 60ml; and The sizes of the central connector ENFit syringe range from 1ml to 60ml. The syringes are provided with transparent or amber color barrel.

The material used of deviec are Polypropylene, Polyisoprene rubber, Polydimethysiloxane(inside surface coating of barrel), Amber additive(for used amber color barrel only), which are also patient-contacting materials for the proposed devices. The time of contact duration is less than 24 hours. The contact level is mucosal membrane, indirect.

The proposed device is sterile or non-sterile, single use. The sterile device was sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of five years.

The proposed device 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. The device has no energy in itself. But the syringe works with infusion pump and extension sets.The syringe is aspirated nutritional formula liquid, connected the extension set. Then user installed it on the infusion pump, and pump fluids into a body enterally in a controlled manner for administer enteral nutrition. The accuracy of graduations for enteral syringes is +/- 4% of expelled volume.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K161141
Classification :II
Product code :PNR
Regulation number :21 CFR 876.5980
Registered Establishment Name: Pentaferte Italia s.r.l.
Address: Loc. Nocella SP 262,I-64012 Campli (TE)-Italy
Product Name: ENFit enteral pump syringes PENTA ENFit™
ENFit enteral pump syringes NUTRIFIT™

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 80369-3:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 3: Connectors for Enteral Applications
ISO 80369-20:2015 Small-Bore Connectors for Liquids And Gases in Healthcare Applications-Part 20: Common Test Methods;
ISO 7886-1:2017 Sterile Hypodermic Syringes for Single Use-Part 1: Syringes for Manual Use;
ISO 7886-2:2020 Sterile Hypodermic Syringes for Single Use-Part 2: Syringes for use with power-driven syringe pumps;
ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
ISO 10993-7:2008, Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices;
ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;
ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device， K161141	Remark
Regulation No.	21CFR 876.5980	21CFR 876.5980	Same
Product Code	PNR	PNR	Same
Class	II	II	Same
Indications for Use	Enteral Pump Syringes deliver nutritional formula to the gastrointestinal system of a patient who is physically unable to eat and swallow. Enteral Pump Syringes 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. Enteral Pump Syringes are intended for neonatal, pediatric and adult use. Enteral Pump Syringes are single use devices.	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.	Same
Environment of Use	Clinical or home care settings	Clinical or home care settings	Same
Configuration	Piston; Plunger; Barrel with ENFit connector; Tip cap	Piston; Plunger; Barrel with ENFit connector; Tip cap	Same
Operation Mode	Syringes can be connected with enteral infusion pump. The user installed it on the infusion pump, and pump fluids into a body enterally in a controlled manner.	These syringes can be connected with enteral infusion pump.The user installed it on the infusion pump, and pump fluids into a body enterally in a controlled manner.	Same
Pump compatibility	Pump compatibility is demonstrated by the in vitro bench tests on ENFit	Pump compatibility is demonstrated by the in vitro bench tests on ENFit	Same

	enteral pump syringes, which show the compliance with the applicable requirements of the ISO 7886-1 and ISO 7886-2.	enteral pump syringes, which show the compliance with the applicable requirements of the ISO 7886-1 and ISO 7886-2.	
Label/labeling	Conform with 21CFR Part 801 Subpart D	Conform with 21CFR Part 801 Subpart D	Same
Product model	Low dose tip ENFit Syringe: 1ml, 3ml, 6ml Standard ENFit Syringe: 6ml, 12ml, 20ml, 35ml, 60ml	10ml, 20 ml, 60 ml	Analysis 1
Product Performance	Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1; ISO 7886-2;	Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1; ISO 7886-2;	Same
Connector type	ISO80369-3, female ENFit connector, low dose tip for 1ml/3ml/6ml syringe, Standard tip for 6ml/12ml/20ml/35ml/60ml syringe, Side connector for 12ml/20ml/35ml/60ml syringe	ISO 80369-3, female ENFit connector	Analysis 3
Patient Contact Material	Barrel:Polypropylene Plunger:Polypropylene Piston:Polyisoprene Lubricant:Polydimethysiloxane Color additives:Amber additive	Polypropylene Ink/Colorants Silicone oil (Polydimethylsiloxane) Latex Free, nontoxic synthetic rubber	Analysis 2
Biocompatibility	Meet the applicable Biocompatibility requirements according to ISO 10993 Cytotoxicity: No Cytotoxicity Skin Irritation: No Irritation Sensitization: No Sensitization	ENFit enteral pump syringes satisfy the applicable Biocompatibility requirements according to ISO 10993	Same
Sterilization Status	Sterile and non-sterile	Sterile; No clear non sterile , but in 510(k) summary is stated that the device were carried out bioburden tests.	Same
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Single Use	Single Use	Single Use	Same

Analysis 1

The proposed device is modified device of ENFit Oral/Enteral Syringe (K190502,cleared July 2, 2019). The change is a operation mode change from manual use to use with infusion pump. The proposed device have

more product available model than predicate device. These product models were tested according to ISO 7886-1 and ISO 7886-2. These product models were conducted to compatibility tests with the recommended infusion pumps. There is available model 0.5ml to 100ml in K143344 of the summary of predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 2

The patient contact material for the predicate devices is difference. According to guidance,Use of International Standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the proposed device is Surface device of mucosal membrane and limited contact. The Cytotoxicity test, Sensitization test, and Irritation test have been performed for proposed device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Analysis 3

There are different connectors in proposed devices. There is not change with ENFit Oral/Enteral Syringe (K190502). These product models were tested according to ISO 80369-3. These product models were conducted to compatibility tests with the recommended infusion pumps. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.