DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2017

Jiangsu Caina Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K161979
Trade/Device Name: ENFit Enteral Syringe
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tubes and Accessories
Regulatory Class: II
Product Code: PNR
Dated: February 15, 2017
Received: February 21, 2017

Dear Diana Hong:

This letter corrects our substantially equivalent letter of March 22, 2017.

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,

Benjamin R. Fisher -S

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)*

K161979

Device Name
ENFit Enteral Syringe

Indications for Use *(Describe)*

The proposed device is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

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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"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."

Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K161979

1. Date of Preparation: 03/17/2017

2. Sponsor Identification

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

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: ENFit Enteral syringe
Common Name: Enteral Feeding Syringe with ENFit Connector
Size: 1ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml

Regulatory Information

Classification Name: Gastrointestinal tube and accessories;
Classification: II;
Product Code: PNR
Regulation Number: CFR 876.5980;
Review Panel: Gastroenterology/Urology;

Indications for Use:
ENFit Enteral Syringe is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

Device Description
The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 1ml~60ml. This device incorporates a female ENFit connector for connection to an enteral access device with male ENFit connector.

The propsoed syringe is 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.

5. Identification of Predicate Device

Predicate device
510(k) Number: K161039
Manufacturer: NeoMed, Inc.
Product Name:
NeoConnector Oral/Enternal Feeding Syringes with ENFit Connector (12ml to 100ml)
NeoConnector Low Dose Tip Oral/Enternal Feeding Syringes with ENFit Connector (0.5ml to 6ml)

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:

- AAMI/CN3 (PS):2014, Small-bore connectors for liquids and gases in healthcare application-Part 3: Connectors for enteral applications;
- ISO 80369-3:2016, Small-bore connectors for liquids and gases in healthcare application-Part 3: Connectors for enteral applications;
- ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare application-Part 20: Common test methods;
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for 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;
- ASTM F 88/F88M-09, Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/F1140-13, Standard test methods for internal pressurization failure resistance of unrestrained packages
- USP37-NF32 <85> Bacterial Endotoxins Limit.
- ISO 7886-1:1993 Sterile hypodermic syringe for syring use-Part 1: Syringe for manual use

Biocompatibility testing has demonstrated the biological safety of the proposed devices which may indirectly contact the patients.

Product performance after Accelerated Aging test and Package Integrity after Accelerated Aging test evaluated the properties of the enteral feeding syringes afteraccelerated aging in support of the labeling.

Connector testing performed on the proposed device included the items listed below, in accordance with ISO 80369-3:2016, Small-bore connectors for liquids and gases in healthcare applications –Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO 80369-3:2016.

Individual test Defined in ISO 80369-3	Requirement Defined in AAMI/CN3 (PS):2014	Test Method Defined in ISO 80369-20
Fluid Leakage	Clause 6.2	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H
Disconnection by unscrewing	Clause 6.7	Annex I

Syringe testing performed on the proposed device included the items listed below, in accordance with ISO 7886-1:1993, Sterile hypodermic syringe for syring use-Part 1: Syringe for manual use, using the test methods provided in ISO 7886-1:1993. The testing demonstrates the proposed devices conform to the requirements of ISO 7886-1:1993.

Individual test Defined in ISO 7886-1:1993	Requirement Defined in ISO 7886-1:1993
Cleanliness	Clause 5
Limits for acidity or alkalinity	Clause 6
Limits for extractable metals	Clause 7
Lubricant	Clause 8
Tolerance on graduated capacity	Clause 9
Graduated scale	Clause 10
Barrel	Clause 11
Piston/plunger assembly	Clause 12
Dead space	Clause 14.1
Freedom from air and liquid leakage past piston	Clause 14.2

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K161039	
Product Code	PNR		PNR	
Regulation Number	CFR 876.5980;		CFR 876.5980;	
Intended Use	The proposed device is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.		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 orally or enterally. It is intended to be used in clinical or home care setting by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.	
Configuration	Barrel with ENFit connector		Barrel with ENFit connector	
	Purple Plunger		Purple Plunger	
	Piston		Piston	
	Tip cap		Tip cap	
Size	Low dose tip ENFit syringe	1ml, 3ml	Low dose tip ENFit syringe	0.5ml-6ml
	Standard ENFit syringe	5ml-60ml	Standard ENFit syringe	12ml-100ml
Sterile	Yes		Yes	
Single Use	Yes		Yes	

Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytoxicity	*No Cytoxicity*
	No Irritation to Skin	*No Irritation to Skin*
	No significant evidence of sensitization	*No significant evidence of sensitization*

Product Comparison Summary

The proposed device and predicate device are intended for patients who require enteral nutrition due to illness or injury which prevents normal chewing and swallowing. These products are enteral syringes that have the same smalll-bore connector, similar intended use and product specification

The difference between the proposed device and predicate device is the size of the syringe; both the proposed device and the predicate device comply with the relevant international Standards. Therefore the differences on syringe size will not raise new problems on safety and effectiveness of the proposed device.

8. Substantially Equivalent (SE) Conclusion

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