August 6, 2019

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

Re: K190502
Trade/Device Name: ENFit Oral/Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: June 21, 2019
Received: July 2, 2019

Dear Diana Hong:

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
Martha W. Betz, Ph.D.
Acting Assistant Division 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)*
K190502

Device Name
ENFit Oral/Enteral Syringe

Indications for Use *(Describe)*
ENFit Oral/Enteral Syringe is indicated for use as a dispenser, a measuring device, and an oral/enteral 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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) 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.

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: K190502

1. Date of Preparation: 08/05/2019

2. Sponsor Identification

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

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: ENFit Oral/Enteral 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:

ENFit Oral/Enteral Syringe is indicated for use as a dispenser, a measuring device, and an oral/enteral 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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

Device Description:

The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 0.5ml to 100ml. It consists of plunger, piston, barrel and tip cap, and used to deliver fluids into the body orally or connected to an enteral access device with male ENFit connector. The syringes (size 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml and 100ml) incorporate a female Standard ENFit connector; the syringes (size 0.5ml, 1ml, 3ml, 5ml and 6ml) incorporate a female low dosing ENFit connector.

There are 2 types of the syringe:
Side connector ENFit syringe and central connector ENFit syringe. The sizes of the Side connector ENFit syringe range from 10ml to 100ml; and central connector ENFit syringe range from 0.5ml to 100ml.

The proposed syringe is sterile or non-sterile. 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 sterile syringes are provided with transparent barrel, and the non-sterile syringes are provided with transparent/ amber color barrel.

5. Identification of Predicate Device

510(k) Number: K161039
Product Name: Oral/Enternal Feeding Syringes with ENFit Connector (12ml to 100ml) and 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:

ISO 80369-3:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 3: Connectors for Enteral Applications
ISO 7886-1:2017 Sterile Hypodermic Syringes for Single Use-Part 1: Syringes for Manual Use;
ISO 80369-20:2015 Small-Bore Connectors for Liquids And Gases in Healthcare Applications-Part 20: Common Test Methods;
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;

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 K161039
Product Code	PNR	PNR
Regulation Number	21CFR 876.5980	21CFR 876.5980
Indications for Use	ENFit Oral/Enteral Syringe is indicated for use as a dispenser, a measuring device, and an oral/enteral 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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) 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	Piston; Plunger; Barrel with ENFit connector; Tip cap	Piston; Plunger; Barrel with ENFit connector; Tip cap
Material	Plunger: polypropylene (PP); Barrel: polypropylene (PP); Piston: polyisoprene	Unknown
Color	Plunger: purple Barrel: transparent and amber color	Plunger: white Barrel: transparent and amber color
Product Size	Low does tip ENFit Syringe: 0.5ml, 1ml, 3ml, 5ml and 6ml	Low dose tip ENFit syringe: 0.5ml~6ml;
	Standard ENFit syringe: 5ml, 6ml, 10ml, 12ml, 20ml, 30ml, 35ml, 50ml, 60ml and 100ml	Standard ENFit syringe: 12ml~100ml;
Product Performance	Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1;	Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1;
Operation Mode	For Manual Use Only	For Manual Use Only
Sterile	Sterile or non-sterile	Sterile or non-sterile
Sterile Method	EO Sterilized	EO Sterilized
SAL	10^{-6}	10^{-6}
Single Use	Single Use	Single Use

The patient contact material for the predicate devices is unknown, and the plunger color is different between the proposed device and predicate device. However, the Cytotoxicity, Irritation, and Sensitization Testing on proposed device were completed according to ISO 10993, the results did not show any adverse effect. Therefore, this difference is not considered to effect substantially equivalency.

9. Substantially Equivalent (SE) Conclusion

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