September 16, 2022

Jiangsu Caina Medical Co., Ltd.
Jianwei Pan
Regulatory Affairs
No. 23, Huanxi Road, Zhutang Town
Jiangyin, Jiangsu 214415
China

Re: K222155
Trade/Device Name: O-ring gasket syringe with ENFit connector (single use or reusable)
Oral/Enteral syringe with ENFit connector (single use or reusable)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: July 15, 2022
Received: July 20, 2022

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,

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)*
K222155

Device Name
O-ring gasket syringe with ENFit connector (single use or reusable)
Oral/Enteral syringe with ENFit connector (single use or reusable)

Indications for Use *(Describe)*
Single use O-ring gasket syringe with ENFit connector (provided sterile and non-sterile):
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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups.

Reusable O-ring gasket syringe with ENFit connector (provided non-sterile):
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 multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

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: K222155

1. Date of Preparation: July 08, 2022

2. Sponsor Identification

**Jiangsu Caina Medical Co., Ltd.**

No.23, Huanxi Road, Zhutang Town, Jiangyin, Jiangsu, 214415, China

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: O-ring gasket syringe with ENFit connector (single use or reusable)
Oral/Enteral syringe with ENFit connector (single use or reusable)

Regulatory Information

Classification Name: Gastrointestinal tube and accessories
Produce Code Name: Enteral syringes with enteral specific connectors
Classification: II
Product Code: PNR
Regulation Number: 21 CFR 876.5980
Review Panel: Gastroenterology/Urology

Indications for Use Statement:
Single use O-ring gasket syringe with ENFit connector (provided sterile and non-sterile):
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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups.

Reusable O-ring gasket syringe with ENFit connector (provided non-sterile):
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 multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

5. Device Description

The proposed device is manual feeding syringe, used as a dispenser, a measuring device, and a fluid transfer device. And it is used to deliver fluids into the body orally or enterally in clinical and non-clinical settings.

There are 2 types of connector for proposed device: Low dose tip ENFit connector(1ml to 6ml) and Standard ENFit connector(12ml to 60ml). The proposed device is standard piston syringe consisting of a plastic hollow barrel with female ENFit connector of ISO 80369-3, plunger, O-ring piston. Connector of 1ml and 3ml syringe situated centrally, connector of other syringe situated eccentrically. All connectors are compatible only with enteral access or accessories having male ENFit connector of ISO 80369-3. The proposed syringes are available in transparent barrel and amber barrel.

The proposed device is provided sterile or non-sterile, single use or reusable. The sterile device is sterilized by Ethylene Oxide Gas (EtO) to achieve a SAL of $10^{-6}$ and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life. The reusable device is for single patient use only.

The proposed device is made with polypropylene and Silica gel. No DEHP, BPA and Natural Rubber Latex are added in the proposed device. The proposed device also has an optional syringe tip cap.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K183540
Product Name: Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and
Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL)

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 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP-NF <151> Pyrogen Test
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-21 standard method for seal strength of flexible barrier materials
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP-NF <85> Bacterial Endotoxins Test
- ISO7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications
- ISO80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

In addition, the following verification or testing is performed to meet the stated performance requirements:

- Microbial Enumeration and Specified Microorganisms Tests report
- Cleaning instructions verification
- Re-use cycle parameters study
- Microbial study in simulation using
- Risk assessment in accordance to ISO 14971
- Dosing Accuracy Testing

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K183540

| ITEM | Proposed Device | Predicate Device<br>K183540 | Comment |
|---|---|---|---|
| Product code | PNR | PNR | Same |
| Regulation No. | 21 CFR 876.5980 | 21 CFR 876.5980 | Same |
| Regulation Name | enteral syringes with enteral specific connectors | enteral syringes with enteral specific connectors | Same |
| Regulation Class | II | II | Same |
| Indications for use | Single use O-ring gasket syringe with ENFit connector (provided sterile and non-sterile):<br>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 body orally or enterally. It is intended to be used in clinical and non-clinical settings by users ranging from clinicians to laypersons in all age groups.<br><br>Reusable O-ring gasket syringe with ENFit connector (provided non-sterile):<br>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 body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only. | Single Use Oral/Enteral Syringes with ENFit Connector (provided sterile and non-sterile): 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 and non-clinical settings by users ranging from clinicians to laypersons in all age groups.<br><br>Reusable Oral/Enteral Syringes with ENFit Connector (provided non-sterile): 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 multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only. | Same |
| Configuration | Piston (gasket type);<br>Plunger;<br>Barrel with integral ENFit connector;<br>Tip cap(optional) | Gasket;<br>Plunger;<br>Barrel with integral ENFit connector | See Comment 1 |
| Product Size | Low does tip ENFit connector Syringe: 1ml, 3ml, 6ml | Low does tip ENFit connector Syringe: 1ml to 6ml | Same |
| | Standard ENFit connector Syringe: | Standard ENFit connector Syringe: | |

| | | | |
|---|---|---|---|
| | 12ml, 20ml, 35ml, 60ml | 12ml- 60ml | |
| Material | Polypropylene<br>Silica gel<br>Polydimethysiloxane<br>Purple color additive | Polypropylene<br>Silicone<br>Polydimethylsiloxane<br>White Colorant | See Comment 2 |
| Expiration Date | 5 years | 3 years | See Comment 3 |
| Sterile | Sterile and non-sterile | Sterile and non-sterile | Same |
| Sterile method | EtO Sterilized(only sterile device) | EtO Sterilized(only sterile device) | Same |
| SAL | $10^{-6}$(only sterile device) | $10^{-6}$(only sterile device) | Same |
| Single use | Single use or single patient use | Single use or single patient use | Same |
| User population | From clinicians to laypersons(Rx and OTC) | From clinicians to laypersons(Rx and OTC) | Same |
| Patient population | In all age groups | In all age groups | Same |
| Environment of Use | clinical and non-clinical settings | clinical and non-clinical settings | Same |
| Performance Testing | Complied with:<br>ISO 80369-3;<br>ISO 7886-1; | Complied with:<br>ISO 80369-3;<br>ISO 7886-1; | Same |
| Biocompatibility | Acute systemic toxicity<br>ISO 10993-11:2017 Third edition | Cytotoxicity: ISO 10993-5;<br>Irritation and Sensitization: ISO 10993-10;<br>Acute systemic toxicity: ISO 10993-11; | Comment 4 |
| | Implantation<br>ISO 10993-6:2016 Third edition | | |
| | Cytotoxicity<br>ISO 10993-5:2009 Third edition | | |
| | Irritation<br>ISO 10993-10:2010 Third edition | | |
| | Pyrogen<br>USP <151> USP- NF2017 | | |
| | Sensitization<br>ISO 10993-10:2010 Third edition | | |
| | Subacute toxicity<br>ISO 10993-11:2017 Third edition | | |

Comment 1

The optional tip cap is used to prevent fluid loss and contamination of syringe contents until ready for use. This added cap does not affect substantially equivalence on safety and effectiveness.

Comment 2

Differences in materials between the predicate and subject device were addressed through Biocompatibility test.

Comment 3

The expiration date for the proposed device is different from predicate device. The proposed devices have been performed 5 years accelerated aging and demonstrated that the aged samples also complied with the requirements of ISO7886-1 and ISO 80369-3. The ability of immediate package of the proposed device to maintain the device in a sterile state for a period of 5 years has been validated in accordance with ASTM F1886/F1886M-16, ASTM F88/F88M-21, ASTM F1929-15. Therefore, this expiration date difference does not affect substantially equivalence on safety and effectiveness.

Comment 4

The biocompatibility for the proposed device is different from predicate device. The contact duration for the proposed device is stated up to 14 day. 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 Pyrogen test, Subacute Systemic Toxicity test, Implantation test are added for evaluation endpoint and meet the requirements of biocompatibility.

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 device. The nonclinical testing demonstrates that the proposed device is as safe, as effective, and performs as well as the predicate device.