January 18, 2024

Jiangsu Caina Medical Co., Ltd.
Camel Zhou
Management Representative
No.23, Huanxi Road, Zhutang Town
Jiangyin, Jiangsu 214415
China

Re: K233190
Trade/Device Name: ENFit Adaptor
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIO
Dated: December 6, 2023
Received: December 14, 2023

Dear Camel Zhou:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233190

Device Name
ENFit Adaptor

Indications for Use *(Describe)*
The ENFit Adaptor is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.

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 6 510(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: K233190

1. Date of Preparation: May 15, 2023

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: ENFit Adaptor

Regulatory Information
Regulation Name: Gastrointestinal tube and accessories
Device Class: II
Product Code: PIO
Regulation Number: 21 CFR 876.5980
Review Panel: Gastroenterology/Urology

Indications for Use Statement:

The ENFit Adaptor is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.

5. Device Description

To facilitate the interconnection between newly-released feeding sets, which are equipped with female ENFit connectors, and the funnel feeding ports of previously-designed enteral feeding tubes, the proposed device is designed with the mating component of an ENFit female connector, designed and tested in accordance with ISO 80369-3 and ISO 80369-20, at one of its ends, and the mating component of a non-ISO 80369-1 compliant funnel feeding port, a stepped tip connector, at its other end. It can prevent an interruption or delay in patient care by allowing fitment of enteral feeding sets with ISO 80369-3 compliant ENFit female connectors to existing enteral feeding tubes with non-ISO 80369-1 compliant end connectors, referred to as "funnel feeding ports" which are still available for use in healthcare setting.

The proposed device is sterile or non-sterile. The sterile device is sterilized by ethylene oxide to achieve a SAL 10^{-6} and supplied in sterility maintenance package which maintain the sterility of the device during the shelf life 5 years.

No DEHP, BPA and Natural Rubber Latex are added in the device.

6. Identification of Predicate Device

Predicate Device
510(k) Number: K140581
Product Name: Cedic Enteral Distal End ENFit Transition Connector

7. Clinical Test Conclusion

Not applicable.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K140581

ITEM	Proposed Device	Predicate Device K140581	Comment
Product code	PIO	PIO	Same
Regulation No.	21 CFR 876.5980	21 CFR 876.5980	Same
Regulation Name	Gastrointestinal tube and accessories	Gastrointestinal tube and accessories	Same

Class	II	II	Same
Indications for use	The ENFit adaptor is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.	The Cedic Enteral Distal End ENFit Transition Connector is intended for connecting an enteral giving set with an ENFit connector to an enteral catheter with funnel.	Same
Configuration	Only one configuration: ENFit Adaptor: designed to connect an enteral giving set equipped with an ENFit female connector to an enteral catheter equipped with soft funnel port.	Three configurations: PGLock female to funnel connector: designed to connect an enteral giving set equipped with an ENFit female connector to an enteral catheter equipped with soft funnel port. Male oral tip syringe to PGLock male connector: designed to connect a syringe equipped with male oral tip to a medication port equipped with an ENFit male connector. Stepped connector to PGLock male connector: designed to connect an enteral giving set equipped with stepped connector to an enteral catheter equipped with an ENFit male connector.	Same The only one configuration of the proposed device is included in the three configurations of predicate devices
Rx vs. OTC	Rx	Rx	Same
Material	ABS PA-757; LDPE 2420H; Purple color additive.	ABS HF 380; LDPE (Riblene MM20); soft PVC (Nakan FMA919N); Remafin Violet PE43076356-ZT (2%).	Different Comment 1
Expiration Date	5 years	3years	Different Comment 2
Sterilization	Sterile or non-sterile	Non-sterile	Different Comment 3
Single use	Yes	Yes	same
Condition of	Healthcare or home settings	Healthcare or home settings	same

Use(Environment)			
User population	Healthcare professionals or lay users and patients after proper training	Healthcare professionals or lay users and patients after proper training	same
Operating Principle	Operate by providing a means of interconnecting incompatible enteral feeding device end fittings together, so that patient enteral feeding can take place when 'new generation' ENFit end fittings need to be connected to previous designs of end fitting	Operate by providing a means of interconnecting incompatible enteral feeding device end fittings together, so that patient enteral feeding can take place when 'new generation' ENFit end fittings need to be connected to previous designs of end fitting	same

Comment 1

The patient contact materials for the proposed device are different from predicate device. 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 external communicating device of surface device, mucosal membrane and limited contact. The Cytotoxicity test, Sensitization test, Intracutaneous reactivity test have been performed for proposed device. Therefore, this material difference does not affect substantially equivalence on safety and effectiveness.

Comment 2

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 ISO80369-3 and ISO 80369-20. 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 ISO 11607 and ISTA 3A. Therefore, this expiration date difference does not affect substantially equivalence on safety and effectiveness.

Comment 3

Compared with the predicate device, the proposed device has added the provision of sterility. The sterile method is EO, and the SAL level is validated at 10^{-6}. The performance after sterilization is tested according to ISO 80369-3 and ISO 80369-20, and the residual level of EO/ECH meet the requirements of ISO 10993-7:2008/Amd.1:2019. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

9. Non-Clinical Test

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:

Performance

- ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications [Including AMENDMENT 1 (2019)].
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods.

  The tests carried out include:
  - Fluid Leakage
  - Stress Cracking
  - Resistance to Separation from Axial Load
  - Resistance to Separation from Unscrewing
  - Resistance to Overriding
  - Disconnection by Unscrewing
  - Connector Incompatibility Test
  - Materials Used for Small-bore Connectors
  - Dimensional analysis
  - Compatibility and Usability Test

In addition, the performance test of stepped tip connector of ENFit Adaptor has been carried out according to Clause V.B of Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications - Guidance for Industry and Food and Drug Administration Staff .Document issued on February 11, 2015 and ISO 20695:2020 Enteral feeding systems - Design and testing.

The tests carried out include:
- Mechanical testing of enteral connectors to assess incompatibility
- Tensile properties
- Liquid leakage
- Flow Rate

Risk assessment

This 510(k) submission includes a copy of the risk assessment for the ENFit Adaptor to demonstrate that risks have been reduced to acceptable levels according to ISO 14971:2019.

Biocompatibility

In accordance with ISO 10993-1, the adaptor is classified as: Surface device, Mucosal membrane, Limited contact (≤ 24 h). The following endpoints were evaluated:

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation.
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

Sterilization, Shipping and Shelf-Life

The subject device has a 5 year shelf life

- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye

penetration.

- ASTM F88/F88M-21 Standard Test 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 <85> Bacterial Endotoxins Test.

10. Substantially Equivalent (SE) Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The ENFit Adaptor is substantially equivalent to the Cedic Enteral Distal End ENFit Transition Connector with respect to the indications for use, target population, treatment method, and technological characteristics.