April 17, 2024

Hangzhou Primecare Medical Co., Ltd.
Li Xuedong
Regulatory Director
Room 408-409, Zancheng Center West, Shangcheng District
Hang zhou, Zhe jiang 310008
China

Re: K240039
Trade/Device Name: Enteral Feeding Sets
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF, KNT,
Dated: March 18, 2024
Received: March 18, 2024

Dear Li Xuedong:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240039

Device Name

Enteral Feeding Sets

Indications for Use *(Describe)*

Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a EnPlus spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.

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.

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510(k) Summary - K240039

Device Trade Name: Enteral Feeding Sets

Common Name: Enteral Feeding Sets

Classification Name: Gastrointestinal tube and accessories

Product Code: KNT, PIF

Regulation: 876.5980

Regulatory Class: Class II

Submitter/Manufacturer:

Hangzhou Primecare Medical Co., Ltd.

Room 408-409, Zancheng Center West, Shangcheng District, Hangzhou Zhejiang 310008 China

Tel: 86-571-81958620

Regulatory Contact: Li Xuedong, Regulatory Director

Predicate Device

Device Trade Name: CONOD Enteral Feeding Sets

510(k) Number: K181276

Classification: Class II, 876.5980, Gastrointestinal tube and accessories

Product Code: KNT, PIF

Device Description

The Enteral Feeding Sets have four models, Enteral Feeding Pump bag Set, Enteral Feeding Pump EnPlus spike Set, Enteral Feeding Gravity bag Set, Enteral Feeding Gravity EnPlus spike Set. The Enteral Feeding Pump bag Set and Enteral Feeding Gravity bag Set both have a structure of a formula bag with 100ml graduations and a protective closure cap. The difference is the former is droved by pump and the latter is droved by gravity. Enteral Feeding Pump EnPlus spike Set and Enteral Feeding Gravity EnPlus spike Set feature a piercing spike (with or without screw cap) used to connect the set to a prefilled container of enteral feeding solution. It is a single-use, non-sterile device.

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Intended Use / Indications for Use

Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a EnPlus spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.

Technological Comparison

- The subject device has the same intended use as the predicate device, dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution, and uses the same technology.

- The subject device has the same technological characteristics and provide the same principle of operation as the predicate device.
- The differences:
  - The predicate device has only 1200ml volume bags, the subject device adds different volumes (1200ml,1000ml,500ml,100ml), Material and intended used are the same.
  - The subject device adds one universal screw cap(with or without) to the spike set to extend the connectivity for different pre-filled formula containers. Material of the screw cap is exactly same as ENPlus spike.
  - The subject device adds a new model that replaces the built-in enteral bag with ENPlus spike and screw cap so that it can connects to the pre-filled nutrition containers instead of having to prepare formula by the user. the ENPlus spike and screw cap introduced in this set is the same as those used in Enteral feeding pump EnPlus Spike sets.
  - The subject device removes the EnFit transitional connector.

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- Shown below is a side by side comparison of the subject device with the predicate device.

Device Characteristic	Subject device	Predicate device (K181276)	Results
Device name	Enteral Feeding Sets	CONOD Enteral Feeding Sets	same
Indications for Use	Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a EnPlus spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.	CONOD Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a piercing spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.	same
Product code	PIF, KNT	PIF, KNT	same
Classification regulation	21 CFR 876.5980	21 CFR 876.5980	same
Device configurations	● Enteral Feeding Pump bag Set (1200ml、1000ml、500ml、100ml) ■ 1200ml/1000ml/500ml/100ml Enteral Bag with closure cap ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Silicone tube ■ Silicone tube connector ■ Warning label ■ EnFit connector ■ Protection cap for the EnFit connector	● CONOD Feeding Pump Set (1200ml) ■ 1200ml Enteral Bag with closure cap ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Silicone tube ■ Silicone tube connector ■ Warning label ■ EnFit connector ■ EnFit transitional connector ■ Protection cap for the transition connector	Similar 1.Adding different bag volume .Material and intended used are the same. 2.Remove the EnFit transitional connector.
	● Enteral Feeding Pump EnPlus spike Set ■ Universal screw cap (with or without) ■ Protection cap for the spike ■ ENPlus spike	● CONOD Safety spike plus Pump Set ■ Protection cap for the spike ■ ENPlus spike ■ PVC tubing ■ Roller clamp	Similar 1.Adding one universal screw cap to the spike set to extend the

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	■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Silicone tube ■ Silicone tube connector ■ Warning label ■ EnFit connector ■ Protection cap for the EnFit connector	■ Drip chamber ■ Silicone tube ■ Silicone tube connector ■ Warning label ■ EnFit connector ■ EnFit transitional connector ■ Protection cap for the transition connector	connectivity for different pre-filled formula containers. 2.Material of the screw cap is exactly same as ENPlus spike. 3.Remove the EnFit transitional connector.
	● Enteral Feeding Gravity bag Set (1200ml、1000ml、500ml、100ml) ■ 1200ml/1000ml/500ml/100ml Enteral Bag with closure cap ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Warning label ■ EnFit connector ■ Protection cap for the EnFit connector	● CONOD Gravity Feeding Set (1200ml) ■ 1200ml Enteral Bag with closure cap ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Warning label ■ EnFit connector ■ EnFit transitional connector ■ Protection cap for the transition connector	Similar 1.Adding different bag volume Material and intended used are the same. 2.Remove the EnFit transitional connector.
	● Enteral Feeding Gravity EnPlus spike Set ■ Universal screw cap (with or without) ■ Protection cap for the spike ■ ENPlus spike ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Warning label ■ EnFit connector ■ Protection cap for the EnFit connector	● CONOD Gravity Feeding Set (1200ml) ■ 1200ml Enteral Bag with closure cap ■ PVC tubing ■ Roller clamp ■ Drip chamber ■ Warning label ■ EnFit connector ■ EnFit transitional connector ■ Protection cap for the transition connector	Different 1.Replacing the built-in enteral bag with ENPlus spike and screw cap so that it can connects to the pre-filled nutrition containers instead of having to prepare formula by the user. the ENPlus spike and screw cap introduced in this set is the same as those used in Enteral feeding pump EnPlus Spike sets

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			2.Remove the EnFit transitional connector.
Design feature	Non DEHP material sets featuring ISO 80369-3:2016 connector	Non DEHP material sets featuring ISO 80369-3:2016 connector	same
Materials	PVC、ABS、Silicone、LDPE、paper	PVC、ABS、Silicone、LDPE、paper	same
Prescription use or not	Prescription use	Prescription use	same
Disposable or not	Disposable for single use	Disposable for single use	same
Intended use time	No longer than 24 hours	No longer than 24 hours	same
Sterile or not	Non-sterile	Non-sterile	same
Shelf-life	5 years	5 years	same
Available tube lengths	Enteral Feeding Pump bag Set: 60cm+157cm Enteral Feeding Pump EnPlus spike Set: 60cm+157cm Enteral Feeding Gravity bag Set: 170cm Enteral Feeding Gravity EnPlus spike Set: 170cm	Pump set: 60cm+157cm Spike set: 60cm+157cm Gravity set: 170cm	Similar

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Summary of Non-Clinical Testing

The non-clinical bench performance testing of the Enteral Feeding Sets is tested according to ISO 80369-3:2016(5-123), ISO20695:2020(9-138), ISO18250-3:2018(5-139), IEC62366-1:2020(5-129), ISO 10993 series of biological standards, Packaging test related standards and the guidance: Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications.

Table 1: Metrology
(include EnFit connector, ENPlus spike & screw cap)

No.	Items	Standards	Acceptance criteria
1	Dimensions (EnFit connector)	ISO 80369-3:2016	Meet the requirements
2	Dimensions (ENPlus spike)	ISO 18250-3:2018	Meet the requirements
3	Dimensions (screw cap)	ISO 18250-3:2018	Meet the requirements

Table 2: Appearance inspection

No.	Items	Standards	Acceptance criteria
1	Deformed parts, Cracking and burr, Incomplete seal or breakage of bag, Kinked tube	Study in-house	None
2	Bag Printing	Study in-house	Present

Table 3: EnFit connector performance testing

No.	Items	Standards	Acceptance criteria
1	Fluid leakage (Leakage by pressure decay)	ISO 80369-3:2016	shall not leak by more than 0.005 $Pa.m^3/s$
2	Stress cracking	ISO 80369-3:2016	No signs of leakage
3	Resistance to separation from axial load	ISO 80369-3:2016	shall not separate from the reference connector
4	Resistance to separation from unscrewing	ISO 80369-3:2016	shall not separate from the reference connector

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5	Resistance to overriding	ISO 80369-3:2016	shall not override the threads or lugs of the reference connector
6	Disconnection by unscrewing	ISO 80369-3:2016	shall separate from the reference connector with an applied unscrewing torque of no greater than 0.35 N·m

Table 4: ENPlus spike & screw cap performance testing

No.	Items	Standards	Acceptance criteria
1	Positive pressure liquid leakage	ISO 18250-3:2018	shall show no signs of leakage
2	Subatmospheric-pressure air leakage	ISO 18250-3:2018	shall not leak by more than 0.005 $Pa.m^3/s$
3	Stress cracking	ISO 18250-3:2018	No signs of leakage
4	Resistance to separation from axial load	ISO 18250-3:2018	shall not separate from the reference connector.
5	Resistance to separation from unscrewing	ISO 18250-3:2018	shall not separate from the reference connector
6	Resistance to overriding	ISO 18250-3:2018	shall not override the threads or lugs of the reference connector

Table 5: Enteral Feeding Sets performance testing

No.	Items	Standards	Acceptance criteria
1	Tensile strength	ISO 20695-2020	shall withstand a tensile force of 15 N before breaking, becoming detached, or cracking
2	Leakage	ISO 20695-2020	shall not show signs of leakage sufficient to form a falling drop of water
3	Flow rate	ISO 20695-2020 Study in-house	Meet the requirements

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Table 6: Packaging performance testing

No.	Items	Standards	Acceptance criteria
1	Visual inspection	ASTMF1886/F1886M-16	No defect of the integrity of seals must be found
2	Seal strength test	ASTM F88/F88M-21 Study in-house	Should not be less than 12 N/ 15mm

Table 7: biological test

No.	Items	Standards	Acceptance criteria
1	Cytotoxicity	ISO 10993-5:2009	Non-Cytotoxic
2	Sensitization	ISO 10993-10:2021	Non-Sensitizer
3	Intracutaneous Irritation	ISO 10993-23:2021	Non-Irritant

Table 8: Usability Study

No.	Items	Standards	Acceptance criteria
1	Usability Study	IEC 62366-1:2020	Meet the requirements

Summary of Clinical Testing

Clinical testing was not required for device evaluation.

Conclusion

The conclusions drawn from the nonclinical testing for the subject device, Enteral Feeding Sets, demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device.