July 3, 2024

Beijing L&Z Medical Technology Development Co., Ltd.
Zhiling Li
Product Registry Specialist
No.8, M2-5 Block, Xinggu Industrial Developing Zone,
Pinggu District
Beijing, 101200
China

Re: K240052
Trade/Device Name: Disposable Enteral Feeding Sets
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF
Dated: January 8, 2024
Received: June 5, 2024

Dear Zhiling Li:

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,

Stephanie Cole -S

for Anthony C. Lee, PhD, MBA
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

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)*

K240052

Device Name

Disposable Enteral Feeding Sets

Indications for Use *(Describe)*

The Disposable Enteral Feeding Sets is intended to be used for enteral feeding nutrition into gastrointestinal tract by connecting with nasogastric tube by gravity. The devices may include a bag to contain the feeding nutrition and/or a spike to connect to a prefilled container. The device is used for 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.

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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510(k) #: K240052

510(k) Summary

Prepared on: 2024-07-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Beijing L&Z Medical Technology Development Co., Ltd.
Applicant Address	No.8, M2-5 Block, Xinggu Industrial Developing Zone, Pinggu District 101200 BEIJING, P.R. CHINA. Beijing 101200 China
Applicant Contact Telephone	15104955040
Applicant Contact	Ms. Zhiling Li
Applicant Contact Email	lizl@lingze.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Disposable Enteral Feeding Sets
Common Name	Gastrointestinal tube and accessories
Classification Name	Gastrointestinal Tubes With Enteral Specific Connectors
Regulation Number	21 CFR 876.5980
Product Code(s)	PIF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142539	Enteralite Infinity Enteral Pump Delivery Set, 1200 ML Enteral Fee	PIF

Device Description Summary

21 CFR 807.92(a)(4)

The proposed device, Disposable Enteral Feeding Sets, is intended to be used for enteral feeding nutrition into gastrointestinal tract by connecting with nasogastric tube by gravity. The devices may include a bag to contain the feeding nutrition and/or a spike to connect to a prefilled container. The device is used for children, adolescents and adults.
The proposed device is provided sterile or non-sterile and single use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Disposable Enteral Feeding Sets is intended to be used for enteral feeding nutrition into gastrointestinal tract by connecting with nasogastric tube by gravity. The devices may include a bag to contain the feeding nutrition and/or a spike to connect to a prefilled container. The device is used for children, adolescents and adults.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indication for Use:
Proposed Device: The Disposable Enteral Feeding Sets is intended to be used for enteral feeding nutrition into gastrointestinal tract by connecting with nasogastric tube by gravity. The devices may include a bag to contain the feeding nutrition and/or a spike to connect to a prefilled container. The device is used for children, adolescents and adults.

Predicate Device: The devices in this product family are used to dispense liquid nutrients (feeding solution) at a preprogrammed pump or user controlled rate. These enteral feeding sets interface with the patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The devices may include a bag to contain the feeding solution and/or a spike to connect to a prefilled container.

Different - Indication for Use
The predicate device can be used for gravity feeding or pump feeding. Therefore, the description of the indication for use of the proposed device differs from that of the predicate device. The proposed device only uses gravity to dispense feeding solution. The indications for use of the proposed device is covered by that of the predicate device. Therefore, this difference will not raise new question on the safety and effectiveness of the proposed device.

Technological Comparison 21 CFR 807.92(a)(6)

Different - Main Configuration
The configuration of the proposed device is the same as that of the predicate device (1200 mL Enteral Feeding Delivery Set), only the naming of the components is different. Therefore, this difference will not raise new question on the new safety and effectiveness of the proposed device.

Different - Bag capacity
The Bag capacity of the proposed device is different from that of the predicate device, and the proposed device offers more options. However, the bag is just used to store the nutritional formula. In addition, the performance test has been performed on the proposed device and the test result of bag part showed that the performance of the proposed device met the pre-determined acceptance criteria. Therefore, this difference on bag capacity will not raise new question on the new safety and effectiveness of the proposed device.

Different - Spike types
The Spike types of the proposed device is different from that of the predicate device, and the proposed device offers more options. However, the spike is just used to connect to a prefilled container. In addition, the performance test has been performed on the proposed device and the test result of spike part showed that the performance of the proposed device met the pre-determined acceptance criteria. Therefore, this difference on bag capacity will not raise new question on the new safety and effectiveness of the proposed device.

Different - Patient-contact material
The patient-contact material of the proposed device is different from that of the predicate device. However, the biocompatibility test has been performed on the proposed device and the test results show that the materials of proposed device will not have the adverse effect on the patient. Therefore, this difference will not raise new question on the new safety and effectiveness of the proposed device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The performance test was conducted on the proposed device to evaluate the performance of the proposed device according to Final product inspection procedure, ISO 20695:2020 Annex C and Annex D, ISO 8536-15:2022 Annex B, ISO 8536-4:2020 Annex B.4,ISO 80369-20:2015 and USP <71> Sterility Tests. The specification BEEGA1 12011, BEEGA1 22211, BEEGA1 32211, BEEGA1 42211, BEEGA1 52211, BEEGA1 62211, BEEGB1 53211, BEEGB1 13011 have already covered the variation of all specifications of Disposable Enteral Feeding Sets. Therefore, the specification BEEGA1 12011, BEEGA1 22211, BEEGA1 32211, BEEGA1 42211, BEEGA1 52211, BEEGA1 62211, BEEGB1 53211, BEEGB1 13011 were selected to conduct the performance test and the test result showed that the aged proposed device met the acceptance criteria. Copies of the test report are provided in as follow:

Tab #24 Chemical Performance Test Report
Tab #25 Physical Performance Test Report
Tab #26 Sterility Test
Exhibit #29 ENfit Physical Performance Test Report