February 16, 2023

Beijing L&Z Medical Technology Development Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K222622
Trade/Device Name: Disposable Infusion Bag for Parenteral Nutrition
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE
Dated: December 21, 2022
Received: January 17, 2023

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,

David Wolloscheck, Ph.D.
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K222622

Device Name
Disposable Infusion Bag for Parenteral Nutrition

Indications for Use *(Describe)*
The Disposable Infusion Bag for Parenteral Nutrition is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set.

The device is not intended to store the fluids for 24 hours or greater.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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# 510(k) Summary - K222622

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K222622

1. Date of Preparation: 2/9/2023

2. Sponsor Identification

**Beijing L&Z Medical Technology Development Co., Ltd.**
N0.8, M2-5 Block, Xinggu Industrial Developing Zone, Pinggu District 101200 BEIJING, P.R. CHINA.

Establishment Registration Number: None

Contact Person: QiuHong Dong
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd.**
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Infusion Bag for Parenteral Nutrition
Common Name: I.V. Container

Regulatory Information
Classification Name: I.V. Container
Classification: II
Product Code: KPE
Regulation Number: 21 CFR 880.5025
Review Panel: General Hospital

5. Identification of Predicate Device

510(k) Number: K101412
Product Name: EVA TPN bag

6. Indications for Use:

The Disposable Infusion Bag for Parenteral Nutrition is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The device is not intended to store the fluids for 24 hours or greater.

7. Device Description:

The proposed device is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. The proposed device is provided sterile and single use.

The proposed device is available in 7 series due to different bag capacities, different tube locations and different tube materials.

| Model | Location of injection port | Location of infusion port | Location of inlet tube | Inlet tube material |
|---|---|---|---|---|
| BEAE series | Below EVA bag | Below EVA bag | Below EVA bag | EVA |
| BEAP series | Below EVA bag | Below EVA bag | Below EVA bag | PVC |
| BEBE series | Below EVA bag | Below EVA bag | Above EVA bag | EVA |
| BEBP series | Below EVA bag | Below EVA bag | Above EVA bag | PVC |
| BECE series | Above EVA bag | Below EVA bag | Above EVA bag | EVA |
| BECP series | Above EVA bag | Below EVA bag | Above EVA bag | PVC |

| | | | | |
|---|---|---|---|---|
| BEDX series | 2 injection ports below EVA bag | 1 infusion port below EVA bag | / | / |

- For model BEAE series, BEAP series, BEBE series, BEBP series, BECE series and BECP series, the device has the inlet tube with spike, injection port and infusion port. The bags are filled by connecting them to containers through standard spikes. Additional medications can be added to the container using an injection port. After filling, the containers can be attached to an intravascular administration set via the infusion port.
- For model BEDX series, the device has two injection ports and one infusion port, and doesn't have the inlet tube with clamp. The bags are filled by injecting them into one of the injection port using a syringe. Additional medications can be added to the container using another injection port. After filling, the containers can be attached to an intravascular administration set via the infusion port.

8. Summary of Technological characteristics

Table 1 General Comparison

| ITEM | Proposed Device | Predicate Device K101412 | Remark |
|---|---|---|---|
| Product Name | Disposable Infusion Bag for Parenteral Nutrition | EVA TPN bag | / |
| Product Code | KPE | KPE | Same |
| Regulation No. | 880.5025 | 880.5025 | Same |
| Class | II | II | Same |
| Classification Name | I.V. Container | I.V. Container | Same |
| Indications for Use | The Disposable Infusion Bag for Parenteral Nutrition is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set.<br>The device is not intended to store the fluids for 24 hours or greater. | The EVA TPN bag is for use in compounding and storage of parenteral nutrition solutions prior to and during administration to a patient using an intravascular administration set. | Same |
| Single-Use | Yes | Yes | Same |

Table 2 Safety and Effectiveness Comparison

| ITEM | Proposed Device | Predicate Device K101412 | Remark |
|---|---|---|---|
| Product Name | Disposable Infusion Bag for Parenteral Nutrition | EVA TPN bag | / |
| Design | The Disposable Infusion Bag for Parenteral Nutrition is provided in two | The empty bags are filled by connecting them to | Different |

<table>
<tr><td></td><td>configurations:<br>- For model BEAE series, BEAP series, BEBE series, BEBP series, BECE series and BECP series, the device has the inlet tube with spike, injection port and infusion port. The bags are filled by connecting them to containers through standard spikes. Additional medications can be added to the container using an injection port. After filling, the containers can be attached to an intravascular administration set via the infusion port.<br>- For model BEDX series, the device has two injection ports and one infusion port, and doesn’t have the inlet tube with clamp. The bags are filled by injecting them into one of the injection port using a syringe. Additional medications can be added to the container using another injection port. After filling, the containers can be attached to an intravascular administration set via the infusion port.</td><td>containers through standard spikes.<br>Additional medications can be added to the container using a medication port.<br>After filling, the containers can be attached to an intravascular administration set via the set port.</td><td></td></tr>
<tr><td>Volume Capacity (mL)</td><td><table><tr><td>Model</td><td>Volume</td></tr><tr><td>BEAE series</td><td>100, 125, 150, 200, 250, 300, 500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 5000</td></tr><tr><td>BEAP series</td><td>100, 125, 150, 200, 250, 300, 500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 5000</td></tr><tr><td>BEBE series</td><td>1500, 2000, 2500, 3000, 3500, 4000, 5000</td></tr></table></td><td>150 to 5000</td><td>Different</td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| | BEBP series | 1500, 2000, 2500, 3000, 3500, 4000, 5000 | | |
| | BECE series | 1500, 2000, 2500, 3000, 3500, 4000, 5000 | | |
| | BECP series | 1500, 2000, 2500, 3000, 3500, 4000, 5000 | | |
| | BEDX series | 100, 125, 150, 200 | | |
| Material | Copolyoxymethylene MC-90 (POM);<br>Low-Density Polyethylene (LDPE);<br>Acrylonitrile-Butadiene-Styrene (ABS);<br>Polypropylene (PP);<br>Ethylene Vinyl Acetate Copolymer (EVA);<br>Poly(vinyl chloride) Resin (PVC);<br>Trioctyl Trimellitate (TOTM);<br>Methyl methacrylate-Acrylonitrile-Butadiene-Styrene Copolymer;<br>Polycarbonate and Isoprene Rubber;<br>Polycarbonate and Butyl Rubber;<br>Acrylic Copolymer;<br>White Masterbatch;<br>Blue Masterbatch | | EVA, phthalate-free ethyl vinyl acetate plastic;<br>Plastic, no components made of natural rubber latex (use of isoprene);<br>PVC with DEHP plasticizer DEHP FREE PVC | Different |
| Biocompatibility | Meet requirements for ISO 10993-1 | | Meet requirements for ISO 10993-1 | Same |
| Sterility | SAL $10^{-6}$, ETO | | SAL $10^{-6}$, ETO | Same |

Different - Design

The design for the proposed device is different from that of the predicate device. The proposed device is provided in two configurations. For model BEAE series, BEAP series, BEBE series, BEBP series, BECE series and BECP series, the proposed device has the same configuration and functions as the predicate device, except that the configuration is named differently. For model BEDX series, the proposed device does not have the inlet tube with clamp. The bag of the proposed device is filled through one of the injection ports. Although the bag is not filled in the same way as the predicate device, the performance test has been performed on the proposed device, and the test result shows that the proposed device can be filled. Therefore, this difference will not raise new questions on safety and

effectiveness of the proposed device.

Different - Volume Capacity

The volume capacity of the proposed device is different from that of the predicate device, and the proposed device offers more options. The bag is used to store nutritional formula. Different volume devices will be selected by physician per patient's condition. Performance test has been performed on the proposed device, and the test result shows that the proposed device will perform as intended. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Different - Material

The 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 an adverse effect on the patient. Therefore, this difference will not raise new question on the new safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 15747-2018 Plastic containers for intravenous injections
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-4:2017 Biological Evaluation of Medical Devices--Part 4: Selection of Tests for Interactions with Blood
- USP <151> Pyrogen Test
- USP <85> Bacterial Endotoxins Test
- 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)]

- USP <71> Sterility Tests
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is substantially equivalent to the predicate K101412.