December 22, 2021

KB Medical (Group) Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.Box 120-119
Shanghai, 200120
China

Re: K210854
Trade/Device Name: Enteral Feeding Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF, PIO

Dear Diana Hong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 16, 2021. Specifically, FDA is updating this SE letter as an administrative correction for an incorrect 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elena Choong, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (301)-796-6161, Elena.Choong@fda.hhs.gov.

Sincerely,

Shanil P. Haugen -S

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

November 16, 2021

KB Medical (Group) Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
CHINA

Re: K210854
Trade/Device Name: Enteral Feeding Set
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PIF, PIO
Dated: August 17, 2021
Received: October 15, 2021

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,

Shanil P. Haugen -S

Shanil P. Haugen, PhD.
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)*
K210854

Device Name
Enteral feeding set

Indications for Use *(Describe)*
Enteral feeding set is intended to use gravity to deliver liquid nutritional formulas or water to patient's enteral access device (feeding tube). The device includes a bag to contain the feeding solution.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K210854

1. Date of Preparation: 09/03/2021

2. Sponsor Identification

KB MEDICAL (GROUP) INC.
9650 RESEARCH DR.SUITE A Irvine, CA USA 92618

Establishment Registration Number: 3015433750

Contact Person: Chunsheng Sheng
Position: Chief Executive Officer (CEO)
Tel: +1(949) 491-0797
Fax: +1(949) 409-0206
Email: susansheng571@gmail.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (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: Enteral feeding set
Common Name: Enteral Feeding Sets

Regulatory Information
Classification Name: Gastrointestinal Tube and Accessories
Classification: II;
Product Code: PIF, PIO
Regulation Number: 876.5980
Review Panel: Gastroenterology/Urology

Indication for Use:
Enteral feeding set is intended to use gravity to deliver liquid nutritional formulas or water to patient's enteral access device (feeding tube). The device includes a bag to contain the feeding solution.

Device Description:
The proposed device is provided non-sterile and single use. It has two types (Type A and Type B). Type A has more component (ENFit transition adapter) than Type B.

The Type A includes 5 models, ENF02G-1000R-T, ENF02G-1000B-T, ENF02G-1200R-T, ENF02G-1200B-T and ENF02-500R-T, which have the same components including 1) filling port, 2) bag, 3) tube, 4) drip chamber, 5) roller clamp, 6) ENFit female connector, 7) ENFit transition adaptor and 8) protecting cover. The difference between the 5 models is the specification of bag and tube.

The Type B includes 5 models, ENF02G-1000R, ENF02G-1000B, ENF02G-1200R, ENF02G-1200B and ENF02-500R, which have the same components including 1) filling port, 2) bag, 3) tube, 4) drip chamber, 5) roller clamp, 6) ENFit female connector and 7) protecting cover. The difference between the 5 models is the specification of bag and tube.

5. Identification of Predicate Device

510(k) Number: K142539
Product Name: Enteralite Infinity Enteral Pump Delivery Set,
1200 ML Enteral Feeding Delivery Set (Selected as predicate device)

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies

with the following standards:

- 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 80369-3:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 3: Connectors for Enteral Applications
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- USP 43 NF 38 <151> Pyrogen Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 SE Comparison

ITEM	Proposed Device	Predicate Device K142539	Remark
Product Name	Enteral feeding set	1200 ML Enteral Feeding Delivery Set	/
Product Code	PIF, PIO	PIF, PIO	Same
Regulation No.	876.5980	876.5980	Same
Class	II	II	Same
Indication for Use	Enteral feeding set is intended to use gravity to deliver liquid nutritional formulas or water to patient's enteral access device (feeding tube). The device includes a bag to contain the feeding solution.	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
Single-Use	Yes	Yes	Same
Main Configuration	Filling port Bag Tube Drip chamber Roller clamp ENFit Female connector ENFit transition adapter (only for Type A) Protecting cover	Inlet port Bag Tube Roller clamp Inlet port cap ENFit connector Christmas Tree shaped transitional stepped connector	Different
Bag capacity	500ml, 1000ml, 1200ml	1200ml	Different
Length of tube (mm)	1800±5	Unknown	Different
Tube inner diameter (mm)	For ENF02G-1000R-T, ENF02G-1200R-T, ENF02-500R-T, ENF02G-1000R, ENF02G-1200R, ENF02-500R: Φ2.85±0.1;	Unknown	Different

	For ENF02G-1000B-T, ENF02G-1200B-T, ENF02G-1000B, ENF02G-1200B: Φ4.0±0.1			
Tube out diameter (mm)	For ENF02G-1000R-T, ENF02G-1200R-T, ENF02-500R-T, ENF02G-1000R, ENF02G-1200R, ENF02-500R: Φ4.05±0.05; For ENF02G-1000B-T, ENF02G-1200B-T, ENF02G-1000B, ENF02G-1200B: Φ6.0±0.1		Unknown	Different
Mechanism of Action	Gravity		Gravity	Same
ENFit connector	Conform with ISO 80369-3		Conform with ISO 80369-3	Same
Patient-contact material	Polyvinyl chloride (PVC) DINCH Cinquasia Pink Heliogen Blue Acrylonitrile Butadiene Styrene (ABS) Polypropylene (PP) Purple		Non-DEHP PVC tubing, extruded film (bags), inlet port and outlet port; Polyethylene inlet port cap; Polycarbonate connector/pump interface (cassette); silicone pump tubing segment; ABS distal (stepped) connector.	Different
Biocompatibility	Cytotoxicity	No cytotoxicity	Complies with ISO 10993	Different
	Skin Irritation	No irritation		
	Sensitization	No sensitization		
	Acute Systemic Toxicity	No acute Systemic Toxicity		
	Subchronic Systemic Toxicity	No subchronic Systemic Toxicity		
	Pyrogen	No pyrogen		
Sterility	Non-sterile		Non-sterile	Same
Shelf life	3-yr		1-yr	Different
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801	Same

The proposed device and the predicate device have the same design and energy source. Although the

material composition of the proposed device and the predicate device are not exactly the same, biological and performance tests have proved that the proposed device will not raise any questions regarding its safety and effectiveness. The details of the differences in technical characteristics are summarized below:

Different - Indication for Use
The predicate device can be used for gravity feeding or pump feeding, and it is available in various configurations with bag or without bag. 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.

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 - Length of tube
The length of the predicate device is unknown. In addition, the performance test has been performed on the proposed device and the test result of tube 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 - Tube inner diameter
The inner diameter of the tube of the predicate device is unknown. The performance test has been performed on the proposed device and the test result of tube part showed that the diameter of the proposed device does not raise new question on the new safety and effectiveness of the proposed device.

Different - Tube outer diameter
The outer diameter of the tube of the predicate device is unknown. The performance test has been performed on the proposed device and the test result of tube part showed that the diameter of the proposed device does 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.

Different - Biocompatibility

The detail biocompatibility testing item of predicate device is unknown. But both of them comply with standard ISO 10993. Therefore, this difference will not raise new question on the new safety and effectiveness of the proposed device.

Different - Shelf life

The shelf life of proposed device and predicate device is different. However, the performance test after aging has been performed on the proposed device and the test result showed that the performance of the proposed device met the pre-determined acceptance criteria. Therefore, this difference will not raise new question on the new safety and effectiveness of the proposed device.

9. Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K142539.