November 9, 2018

Jiangsu Kangbao Medical Equipment Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K182649
Trade/Device Name: Enteral Feeding Syringes with Enfit Connectors
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: September 19, 2018
Received: September 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S
2018.11.09 16:55:01 -05'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K182649

Device Name

Enteral Feeding Syringes with Enfit Connectors

Indications for Use *(Describe)*

Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182649

1. Date of Preparation: 11/06/2018

2. Sponsor Identification

Jiangsu Kangbao Medical Equipment Co., Ltd
78#, North Suzhong Road, Baoying, Yangzhou, 225800, China.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Enteral Feeding Syringes with Enfit Connectors
Model: 1ml, 2.5ml, 5ml, 10ml, 20ml, 60ml and 100ml
Classification Name: Gastrointestinal tube and accessories
Classification: II
Product Code: PNR
Regulation Number: 21 CFR 876.5980
Review Panel: Gastroenterology/Urology

Indications for Use:
Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.

Device Description
The proposed device, Enteral Feeding Syringes with ENfit Connectors, is provided sterile, single use. It has 3 components: (1) barrel, (2) plunger, and (3) piston.

The Enteral Feeding Syringes with ENfit Connectors is available in various size, including 1ml, 2.5ml, 5ml, 10ml, 20ml, 60ml and 100ml. In addition, it contains low dose enteral specific connectors.

The Enteral Feeding Syringes with ENfit Connectors is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K161039
Manufacturer: NeoMed, Inc.
Product Name: NeoConnector Oral/Enternal Feeding Syringes with ENFit Connector (12ml to 100ml)
NeoConnector Low Dose Tip Oral/Enternal Feeding Syringes with ENFit Connector (0.5ml to 6ml)

6. Non-Clinical Test Conclusion

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:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use;
- ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

In addition, the dimension analysis, dosing accuracy test and connector incompatibility test have been conducted to demonstrate the proposed device complies with these requirement.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Substantially Equivalent Comparison

ITEM	Proposed Device	Predicate Device K161039
Product Code	PNR	PNR
Regulation Number	21 CFR 876.5980	21 CFR 876.5980
Class	II	II
Indications for Use	Enteral Feeding Syringe with ENFit Connector is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in all age groups.	The device is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care setting by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.
Configuration	Piston; Plunger; Barrel with ENFit connector	Piston; Plunger; Barrel with ENFit connector

Single Use	Yes	Yes
Operation Mode	Manual Use	Manual Use
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801
Size	1ml, 2.5ml, 5ml, 10ml, 20ml, 60ml and 100ml	0.5~100ml
Performance	Complies with: ISO 7886-1 ISO 80369-3	Complies with: ISO 7886-1 ISO 80369-3
Patient-contact component and material		
Barrel	Polypropylene (PP)	Unknown
Plunger	Polypropylene (PP)	Unknown
Piston	Polyisoprene	Unknown
Color additive	Pigment	Unknown
Biocompatibility		
Cytotoxicity	No Cytotoxicity	No Cytotoxicity
Skin Irritation	No Irritation to Skin	No Irritation to Skin
Sensitization	No significant evidence of sensitization	No significant evidence of sensitization
Sterilization		
Method	EO Sterilized	EO Sterilized
SAL	10^{-6}	10^{-6}
Endotoxin Limit	20 EU per device	20 EU per device

The specifications of proposed device and predicate device are different, however, both of them comply with the same recognized standards. Therefore the differences on syringe size will not raise new problems on safety and effectiveness of the proposed device. In addition, the patient-contact components of the proposed device are same as those of the predicate device, although the patient-contacting materials of the predicated device are unknown, the proposed device and the predicated devices are biocompatible and conforms to ISO 10993 series standards. Therefore, the proposed device is claimed to be substantially equivalent to the predicate devices.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.