May 1, 2020

Shanghai Kindly Enterprise Development Group Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 200120
CHINA

Re: K192179
Trade/Device Name: Oral/Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: March 20, 2020
Received: March 24, 2020

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192179

Device Name
Oral/Enteral Syringe

Indications for Use *(Describe)*
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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K192179

1. Date of Preparation: 04/30/2020

2. Sponsor Identification

Shanghai Kindly Enterprise Development Group Co., Ltd.
No.658 Gaochao Road, 201803 Shanghai, China

Establishment Registration Number: 3004577167

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3. Designated Submission Correspondent

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

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Fax: +1-360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Oral/Enteral Syringe
Common Name: Oral/Enteral Syringe;

Regulatory Information

Classification Name: Gastrointestinal Tube and Accessories;
Classification: II;
Product Code: PNR;
Regulation Number: 21CFR 876.5980;
Review Panel: Gastroenterology/Urology;

Indication for Use Statement:

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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

Device Description:

The proposed device is a disposable enteral feeding syringe provided two models, including Type A and Type B, the main difference is the piston. The piston of Type A is rubber stopper made of isoprene rubber, and the piston of Type B is rubber pad made of silicone rubber.

The proposed device consists of a syringe barrel, syringe plunger and piston (rubber stopper or rubber pad). They are available in 1ml, 3ml, 5ml, 10ml, 20ml, and 60ml.

The enteral syringes are sterilized by Ethylene Oxide to achieve a SAL of 10^{-6} and supplied maintenance package which could maintain the sterility of the device during the shelf life of five years.

5. Identification of Predicate Device

510(k) Number: K161039
Product Name: Oral/Enteral Syringe with ENFit® connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (0.5 mL 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 80369-3:2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications-Part 3: Connectors for Enteral Applications;
- ISO 7886-1:2017 Sterile Hypodermic Syringes for Single Use-Part 1: Syringes for Manual Use;
- 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;
- ISO 10993-7:2008, Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff

In addtion, dose accuracy testing is conducted to demonstrate the enteral syringes are accurate to ±10% when the syringe is filled with a minimum dose of 20% of the overall syringe capacity.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K161039
Product Code	PNR		PNR
Regulation Number	21CFR 876.5980		21CFR 876.5980
Indication for Use	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.		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	Barrel; Plunger (Rubber Stopper or Rubber Pad); Piston		Piston; Plunger; Barrel with ENFit connector; Tip cap
Operation Mode	For Manual Use Only;		For Manual Use Only;
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801
Product Performance	Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1;		Complied with: ISO 80369-3; ISO 80369-20; ISO 7886-1;
Product Size	Type A: Low dose:1ml, 3ml, ; Standard: 5ml, 10ml, 20ml, 60ml		Low dose tip ENFit syringe: 0.5ml~6ml;
	Type B: Low dose: 1ml, 3ml; Standard: 5ml, 10ml, 20ml, 60ml		Standard ENFit syringe: 12ml~100ml;
Sterile	EO Sterilized		EO Sterilized
	10^{-6}		10^{-6}
Biocompatibility	Cytotoxicity	No Cytotoxicity	Conform with ISO 10993
	Skin Irritation	No Irritation	
	Sensitization	No Sensitization	

9. Substantially Equivalent (SE) Conclusion

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