June 30, 2021

Ningbo Tianyi Medical Appliance Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K211025
Trade/Device Name: Oral/Enteral Syringe with ENFit connector
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: April 2, 2021
Received: April 6, 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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211025

Device Name
Oral/Enteral Syringe with ENFit connector

Indications for Use *(Describe)*
The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) 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: K211025

1. Date of Preparation: 06/10/2021

2. Sponsor Identification

Ningbo Tianyi Medical Appliance Co., Ltd.
No.788, Mozhi North Road, Tourism Resort, Dongqian Lake, 315121 Ningbo, PEOPLE'S REPUBLIC OF CHINA

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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

4. Identification of Proposed Device

Trade Name: Oral/Enteral Syringe with ENFit connector
Common Name: Enteral Syringe with Enteral Specific connector

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:
The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) in all age groups.

Device Description
The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 0.5ml to 60ml. It consists of plunger, piston, barrel and tip cap, and used to deliver fluids into the body orally or connected to an enteral access device with male ENFit connector. The syringes (size 12ml, 20ml, 35ml and 60ml) incorporate a female Standard ENFit connector; the syringes (size 0.5ml, 1ml, 3ml, 6ml) incorporate a female low dosing ENFit connector.

There are 2 types of the syringe:
Side connector ENFit syringe and central connector ENFit syringe. The sizes of the central connector tapered syringe range from 0.5ml and 1ml; and side connector ENFit syringe range from 3ml to 60ml.

The proposed syringe is sterile or non-sterile. Sterile device was 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 three years.

5. Identification of Predicate Device

510(k) Number: K161039
Product Name: Oral/Enternal Feeding Syringes with ENFit Connector (12ml to 100ml) and 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 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
- ISO 14971:2007 Medical Devices-Application of Risk Management to Medical Devices;
- 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;
- 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.

In addition, 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. Summary of Technology Characteristics

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K161039	Remark
Product Name	Oral/Enteral Syringe with ENFit connector	Oral/Enternal Feeding Syringes with ENFit Connector (12ml to 100ml) and Low Dose Tip Oral/Enternal Feeding Syringes with ENFit Connector (0.5ml to 6ml)	/
Product Code	PNR	PNR	Same
Regulation Number	21CFR 876.5980	21CFR 876.5980	Same
Indications for Use	The device is intended for use as a dispenser, a measuring device and an oral fluid transfer device. It is intended to be used to deliver fluids into the body orally or enterally. It is intended to be used in clinical or home care settings by operators ranging from qualified medical practitioners to laypersons (under the supervision of a qualified medical practitioners) 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.	Same
Configuration	Piston; Plunger; Barrel with ENFit connector; Tip cap	Piston; Plunger; Barrel with ENFit connector; Tip cap	Same
Single Use	Single Use	Single Use	Same
Product Size (nominal volumes)	Low dose tip ENFit syringe: 0.5ml, 1ml, 3ml, 6ml;	Low dose tip ENFit syringe: 0.5ml~6ml;	Different
	Standard ENFit syringe: 12ml, 20ml, 35ml, 60ml;	Standard ENFit syringe: 12ml~100ml;	
Product Performance	Complied with: ISO 80369-3 ISO 80369-20 ISO 7886-1	Complied with: ISO 80369-3 ISO 80369-20 ISO 7886-1	Same
Material			
Barrel	Polypropylene (PP)	Unknown	Different

Plunger	Polypropylene (PP) and white pigment		
Piston	Silicone rubber		
Tip Cap	Polypropylene (PP) and Orange pigment Or polypropylene (PP) and purple pigment		
Biocompatibility			
Cytotoxicity	No Cytotoxicity	Conform with ISO 10993	Similar
Skin Irritation	No Irritation		
Sensitization	No Sensitization		
Sterile	Sterile or non-sterile	Sterile or non-sterile	SE
Sterile Method	EO Sterilized	EO Sterilized	SE
SAL	10^{-6}	10^{-6}	SE

Different - Product Size

The product size for proposed device is different from predicate device. The proposed device includes 8 sizes, 0.5 ml, 1ml, 3ml, 6ml, 12ml, 20ml, 35ml, 60ml, all of which are covered by predicative device. In addition, this difference is just in infusion capacity and dose not effect indication for use, and the physician can select by per patient's condition. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Different- Material

The material for the predicate devices is unknown. However, the biocompatibility test has been performed on proposed device according to ISO 10993, the result does not show any adverse effect which can demonstrate the safety of proposed device. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Similar- Biocompatibility

The biocompatibility of proposed device and predicate device is similar. Both of them comply with standard ISO 10993, the result does not show any adverse effect which can demonstrate the safety of proposed device. Therefore, this difference does not raise new safety and effectiveness issues for the device.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission, the Oral/Enteral Syringe with ENFit Connector is as safe, as effective, and performs as well

as or better than the legally marketed predicative device cleared under K161039.