June 28, 2021

Shantou Wealy Medical Instrument Co., Ltd.
% Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500#Century Ave
Shanghai, Shanghai 200122
CHINA

Re: K203410
Trade/Device Name: ENFit Disposable Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: May 27, 2021
Received: May 27, 2021

Dear Eva Li:

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)*
K203410

Device Name
ENFit® Disposable Enteral Syringe
（Model：WE1mlLD, WE2.5mlLD, WE5mlLD, WE10ml, WE20ml, WE30ml, WE60ml, WE100ml)

Indications for Use *(Describe)*
Wealy ENFit® Disposable Enteral Syringe 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 setting 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.

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

A. Applicant

Shantou Wealy Medical Instrument Co., Ltd.
Address: North Jinhuan Road (near of Qishan Mid-school) 515064 Shantou, China
Contact Person: Yang Songling
Tel：+8615816758600
Fax：0086-754-82121654

Date Prepared: June 27, 2021

Submission Correspondent
Primary contact: Ms. Eva Li
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: eatereva@hotmail.com
Secondary contact: Mr. Raymond Luo
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device

Trade Name: **ENFit® Disposable Enteral Syringe**
Common Name: Enteral feeding Syringe with ENFit Connector
Model：WE1mlLD, WE2.5mlLD, WE5mlLD, WE10ml, WE20ml, WE30ml, WE60ml, WE100ml

Regulatory Information
Classification Name: Gastrointestinal tube and accessories
Regulatory Class: 2
Product code: PNR
Regulation Number: 876.5980
Device Panel: Gastroenterology/Urology

C. Predicate device:

K161979
ENFit Enteral Syringe
Jiangyin Caina Technology Co, Ltd.

Shantou Wealy Medical Instrument Co., Ltd.
North Jinhuan Road(near Qishan mid-school), 515064 Shantou, China

D. Indications for Use:

Wealy ENFit® Disposable Enteral Syringe 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 setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.

E. Device Description:

The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 1ml~100ml. This device incorporates a female ENFit® connector for connection to an enteral access device with male ENFit® connector.
The proposed syringe 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 three years.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Shantou Wealy Medical Instrument Co., Ltd.	Jiangyin Caina Technology Co, Ltd.	——
510(K) number	K203410	K161979	——
Product Code	PNR	PNR	Same
Regulation Number	CFR 876.5980	CFR 876.5980	Same
Indications for Use	Wealy ENFit™ Enteral Syringe 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 setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.	The proposed device 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 setting by users ranging from laypersons (under the supervision of a clinician) to clinicians, in all age groups.	Same
Configuration	Barrel with ENFit connector	Barrel with ENFit connector	Similar*
	Purple Plunger	Purple Plunger	

	Piston		Piston		
			Tip cap		
Size	Low dose tip ENFit™ syringe	1ml, 2.5ml, 5ml	Low dose tip ENFit™ syringe	1ml,3ml	Similar*
	Standard ENFit™ syringe	10ml-100ml	Standard ENFit™ syringe	5ml-60ml	
Sterile	Yes		Yes		Same
Single use	Yes		Yes		Same
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards		Conforms to the requirement of ISO 10993 series Standards		Same
	No Cytoxicity		No Cytoxicity		
	No Irritation to Skin		No Irritation to Skin		
	No significant evidence of sensitization		No significant evidence of sensitization		

***Similar discussion**

The proposed device don't configure the tip cap, it will not affect the safety and effectiveness of the proposed device.

The size of the proposed device of the low dose tip syringe or standard syringe is similar, all the size of the proposed are pass the acceptance criteria of the related performance standard requirements, so it will not affect the safety and effectiveness of the proposed device.

G. Summary of Non-Clinical Performance Testing

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 application-Part3: Connectors for enteral applications;
- ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare application-Part 20: Common test methods;
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for 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 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ASTM F 88/F88M-09, Standard test method for seal strength of flexible barrier materials;
- USP38-NF33 <85> Bacterial Endotoxins Limit.
- ISO 7886-1:2017 Sterile hypodermic syringe for single use-Part 1: Syringe for manual

Shantou Wealy Medical Instrument Co., Ltd.
North Jinhuan Road(near Qishan mid-school), 515064 Shantou, China

use

Biocompatibility testing has demonstrated the biological safety of the proposed devices which may indirectly contact the patients.

Product performance after Real-time Aging test and Package Integrity after Accelerated Aging test evaluated the properties of the enteral feeding syringes after accelerated aging in support of the labeling.

Connector testing performed on the proposed device included the items listed below, in accordance with ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications –Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods. The testing demonstrates the proposed devices conform to the requirements of ISO80369-3:2016.

Table2：Testing Item according ISO 80369-3:2016

Individual test Defined in ISO 80369-3:2016	Test Method Defined in ISO 80369-20:2015
Fluid Leakage	Annex B
Sub-atmospheric pressure Air Leakage	Annex D
Stress Cracking	Annex E
Resistance to separation from axial load	Annex F
Resistance to separation from unscrewing	Annex G
Resistance to overriding	Annex H
Disconnection by unscrewing	Annex I

Syringe testing performed on the proposed device included the items listed below, in accordance with ISO 7886-1:2017 Sterile hypodermic syringes for single use-Part 1: Syringe for manual use, using the test methods provided in ISO 7886-1:2017. The testing demonstrates the proposed devices conform to the requirements of ISO 7886-1:2017.

Table3：Testing Item according ISO 7886-1:2017

Individual test Defined in ISO 7886-1:2017	Requirement Defined in ISO 7886-1:2017
Appearance	Clause 5
Overall Length of Scale to Norminal Capacity Line	Clause 9.3
Push-button Distance	Clause 11
Force to Operate the Plunger	Clause 13.3
Freedom from air and liquid leakage past piston	Clause 13.2
Limits for Acidity or Alkalinity	Clause 6.2
Limits for Extractable Metals	Clause 6.3
Tolerance on graduated capacity	Clause 8
Dead Space	Clause 13.1
Lubricant	Clause 7
Cleanliness	Clause 5
Graduated Scale	Clause 9

Barrel	Clause 11
Piston/Plunger Assembly	Clause 13

H. Summary of Clinical Performance Test

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, ENFit Enteral Syringe cleared under K161979.