August 27, 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: K203613
Trade/Device Name: ENFit Reusable Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: July 30, 2021
Received: July 30, 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 control's 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)*
K203613

Device Name
ENFit® Reusable Enteral Syringe

Indications for Use *(Describe)*
The ENFit® Reusable 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 body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

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

A. Applicant

Shantou Wealy Medical Instrument Co., Ltd.
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Fax：0086-754-82121654

Date Prepared: July 27, 2021

Submission Correspondent
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Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device

Trade Name: **ENFit® Reusable Enteral Syringe**
Common Name: Enteral Syringe with Enteral Specific connector
Model：1mlLD, 2.5mlLD, 5ml, 10ml, 20ml, 60ml
Product Series Code：WR

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

C. Predicate device:

K183540
Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL)
NeoMed, Inc.

D. Intended use of the device:

The ENFit® Reusable 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 body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.

E. Device Description:

The proposed device with Enfit® connector（1ml-60ml）are standard piston style syringes consisting of syringe barrel with integral EnFit syringe tip, syringe plunger and ring type piston. The proposed device are supplied non-sterile, and reusable. The sizes rang from 1ml to 60ml nominal capacity. The integral syringe tip is a female ENFit connector which is compatible only with enteral access devices or accessories having ENFit compliant or compatible male connectors to form a dedicated system that prevents wrong-route administration of fluids.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device		Predicate Device		Comparison
Manufacturer	Shantou Wealy Medical Instrument Co., Ltd.		NeoMed, Inc.		——
510(K) number	K203613		K183540		——
Product Code	PNR		PNR		Same
Regulation Number	CFR 876.5980		CFR 876.5980		Same
Intend use	The ENFit® Reusable 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 body orally or enterally. It is intended to be used multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.		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 multiple times in non-clinical settings by users ranging from clinicians to laypersons in all age groups. The device is indicated for single patient use only.		Same
Configuration	Barrel with ENFit connector		Barrel with ENFit connector		Same
	Purple Plunger		Purple Plunger		
	Piston		Piston		
Size	Low dose tip ENFit™ syringe	1ml, 2.5ml,	Low dose tip ENFit™ syringe	1ml-6ml	Similar*

	Standard ENFit™ syringe	5ml-60ml	Standard ENFit™ syringe	12ml-60ml	
Sterile	No		No		Same
Reusable	Yes		Yes		Same
Biocompatibility	No Cytotoxicity		No Cytotoxicity		Same
	No Irritation and Sensitization		No Irritation and Sensitization		
	No Acute Toxicity		No Acute Toxicity		

***Similar discussion**

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. 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 following performance tests are conducted:

- Finished Device
  - Risk management report in accordance with ISO 14971:2007 Medical devices - Application of risk management to medical devices
  - Summary of the Usability testing for ENfit Reusable Enteral Syringe(human factor and usability validation)
  - Performance testing with ISO 7886-2:2020 “Sterile hypodermic syringes for single use Part 2: Syringes for use with power-driven syringe pumps
    ——Appearance
    ——Pump Force
    ——Short-term Flow Rate Error
    ——Syringe Compliance
    ——Syringe Design critical dimension
- Reusability
  - Cleaning Instructions Validation and Use Cycle Parameters Study
- Biocompatibility
  - 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 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- Shelf life
  - Package verification test report
  - Bench test after real-time aging（ISO 80369-3:2016, Small-bore connectors for liquids and gases in healthcare application-Part3: Connectors for enteral applications）
    ——Fluid Leakage

——Sub-atmospheric Pressure Air Leakage
——Stress Cracking
——Resistance to Separation from Axial Load
——Resistance to Separation from Unscrewing
——Resistance to Overriding
——Disconnection by Unscrewing

- Bench test after real-time aging（ISO 7886-1:2017 Sterile hypodermic syringe for single use-Part 1: Syringe for manual use）
  ——Appearance
  ——Overall Length of Scale to Nominal Capacity Line
  ——Push-button Distance
  ——Force Required to Operate Plunger
  ——Freedom from Air and Liquid Leakage past Piston
  ——Limits for Acidity or Alkalinity
  ——Limits for Extractable Metals
  ——Tolerance on Graducated Capacity
  ——Maximum Dead Space

➢ Finished Device performance Test

- Critical Dimension verification
- Ink Adhesion
- Bench test（ISO 80369-3:2016, Small-bore connectors for liquids and gases in healthcare application-Part3: Connectors for enteral applications）
  ——Fluid Leakage
  ——Sub-atmospheric Pressure Air Leakage
  ——Stress Cracking
  ——Resistance to Separation from Axial Load
  ——Resistance to Separation from Unscrewing
  ——Resistance to Overriding
  ——Disconnection by Unscrewing
- Bench test（ISO 7886-1:2017 Sterile hypodermic syringe for single use-Part 1: Syringe for manual use）
  ——Appearance
  ——Overall Length of Scale to Nominal Capacity Line
  ——Push-button Distance
  ——Force Required to Operate Plunger
  ——Freedom from Air and Liquid Leakage past Piston
  ——Limits for Acidity or Alkalinity
  ——Limits for Extractable Metals
  ——Tolerance on Graduated Capacity
  ——Maximum Dead Space
  ——Quantity of Lubricant

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

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

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Oral/Enteral Syringes with ENFit® connector (12 mL to 60 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (1 mL to 6 mL) cleared under K183540.