September 12, 2020

Shinva Ande Healthcare Apparatus Co., Ltd.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No. 26 Quinglan Street,
Panyu District
Guangzhou, 510006
CHINA

Re: K193657
Trade/Device Name: Disposable Enteral Feeding Syringe with Enfit Connector
Classification Number: 21 CFR 876.5980
Classification Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PNR
Dated: August 5, 2020
Received: August 10, 2020

Dear Mike Gu:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193657

Device Name
Disposable Enteral Feeding Syringe with Enfit Connector

Indications for Use *(Describe)*

The Disposable 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 feeding 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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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Secondary Contact Person:	Xiaolei Tian R&D Director SHINVA ANDE Healthcare Apparatus Co., Ltd. Tel: (+86)-533-3917821 Fax: (+86)- 533- 3918218
Date prepared	Sep 12, 2020

II. DEVICE

Name of Device:	Disposable Enteral Feeding Syringe with Enfit Connector
Common Name:	Disposable Enteral Feeding Syringe with Enfit Connector
Model/size:	1ml, 2 ml,2.5 ml,3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml

Classification Number:	21 CFR 876.5980
Classification Name:	Gastrointestinal tube and accessories
Device Panel	Gastroenterology/Urology
Regulatory Class:	II
Product Code:	PNR

III. PREDICATE DEVICE

Predicate device K161979, ENFit Enteral Syringe

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The proposed device is a disposable enteral feeding syringe provided in a variety of size from 1ml-60ml (1ml, 2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml and 60ml). The device is composed by barrel with ENFit connector, piston (plunger and plunger stopper), lubricant and tip cap (with or without). The piston is made of polyisoprene synthetic rubber, without DEHP or natural latex. This device incorporates a female ENFit connector for connection to an enteral access device with a male ENFit connector.

They are two types of syringe:

Side connector ENFit syringe and central connector ENFit syringe. The size of the central connector ENFit syringes range from 1ml to 5ml, and they are the low dose tip syringes; and side connector ENFit syringes range from 10ml to 60ml, and they are the standard syringes.

The Disposable Enteral Feeding Syringe with Enfit Connector relies on the interference matching between piston and inner chamber wall of the barrel to ensure the sealing of liquid in the inner chamber of the barrel. The plunger and the plunger stopper constitute a sealing assembly. By pushing and pulling the plunger, the plunger stopper

can be driven to move freely inside the barrel, similar to the piston structure, so as to realize the suction and infusion of fluid.

The proposed syringe is 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 of five years.

V. INDICATION FOR USE

The Disposable 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 feeding 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Disposable Enteral Feeding Syringe with Enfit Connector has the same technological characteristics and fundamental design as the predicate devices. The Disposable Enteral Feeding Syringe with Enfit Connector and the predicate devices are all designed to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow.

The Disposable Enteral Feeding Syringe with Enfit Connector has same indications for use, patient population with the predicates.

At a high level, the subject and predicate device are based on the following same technological elements:

- They are all disposable for single use.
- Their operation mode are all manual use.

- They all have the same configuration that composed by barrel with ENFit connector, piston (plunger and plunger stopper), lubricant and tip cap.
- Their connection type is the small-bore connector featuring ISO 80369-3:2016/AMD 1:2019, Small-Bore Connectors for Liquids and Gases in Healthcare Applications - Part 3: Connectors For Enteral Applications.

The subject device has different sizes compared with the predicate device in low dose and standard dose type. This difference does not raise concerns of safety and effectiveness.

Therefore, the Disposable Enteral Feeding Syringe with Enfit Connector are substantially equivalent to the cleared predicate device (K161979).

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Disposable Enteral Feeding Syringe with Enfit Connector was evaluated in accordance with the FDA Bguidance “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” and ISO 10993-1:2009 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process,” as recognized by FDA. The following tests were performed, as recommended:

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity

The Disposable Enteral Feeding Syringe with Enfit Connector contacts indirectly with the human body for a duration of less than 24 hours.

Sterilization and shelf life testing

The sterilization method has been validated according to ISO 11135:2014 Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices, which has thereby determined the routine control and monitoring parameters. The shelf life of the Disposable Enteral Feeding Syringe with Enfit Connector is determined based on the accelerated aging test. And after the accelerated aging test, the performance test and package integrity test performed on the proposed device.

Bench performance testing

Connector testing performed on the proposed device, in accordance with ISO 80369-3:2016/AMD 1:2019, 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 ISO 80369-3:2016/AMD 1:2019.

Syringe testing performed on the proposed device in accordance with ISO 7886-1:2017, sterile hypodermic syringes for single use — Part 1: Syringes for manual use. The testing demonstrates the proposed device conform to the requirements of ISO 7886-1: 2017.

Aging performance and sterile packaging integrity tests were also performed.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the proposed device Disposable Enteral Feeding Syringe and its predicate devices, no clinical studies were needed to support this 510(k) Premarket Notification.

VIII. CONCLUSION

The proposed device Disposable Enteral Feeding Syringe with Enfit Connector is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.