September 28, 2020

Jiangsu Shenli Medical Production Co., Ltd
% Charlie Mack
Principal Engineer
International Regulatory Consultants
2950 E Lindrick Drive
Chandler, AZ 85249

Re: K200557
Trade/Device Name: Enteral Feeding Syringes with ENfit connector
Model: 10 ml; 60 ml control ring
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and accessories
Regulatory Class: II
Product Code: PNR
Dated: August 17, 2020
Received: August 21, 2020

Dear Charlie Mack:

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)*
K200557

Device Name
Enteral Feeding Syringes with ENFit connector
Model: 10 ml; 60 ml control ring

Indications for Use *(Describe)*
The device is indicated for use as a dispenser, measuring device, and 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) to 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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江苏神力医用制品有限公司
Jiangsu Shenli Medical Production Co,Ltd

K200557 510(k) SUMMARY

Preparation Date:	September 26, 2020
Manufacturer's Name and Address:	Jiangsu Shenli Medical Production Co., Ltd. No 20, Changzheng Road, Zhenglu, Changzhou City, Jiangsu Province, China 213111
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4838
Email Address:	charliemack@irc-us.com
Trade Name:	Enteral Feeding Syringes with ENFit Connector Model: 10ml, 60ml control ring
Common Name(s):	Enteral syringes with enteral specific connectors
Regulation Name(s):	Gastrointestinal Tube and Accessories
Regulation Number(s):	21CFR876.5980
Product Code:	PNR
Regulatory Class:	Class II
Device Panel:	Gastroenterology/Urology
Predicate Device:	NeoMed Inc., Oral/Enteral Syringes with ENFit connector (12 mL to 100 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® Connector (0.5 mL to 6 mL)- K161039

Device Description:

The device is an enteral feeding syringe for single use. The devices are piston-style syringes consisting of a syringe barrel, syringe plunger, syringe gasket, and syringe cap. The device incorporates a female ENFit connector designed to be compatible only with enteral access devices or accessories. It has ENFit compliant or compatible male connectors to form a dedicated system that prevents wrong-route administration of fluids.

The device is a disposable syringe made of the following components:

1. **Plunger**: The Plunger is a piston having a longitudinal shaft that is mechanically received into the proximal syringe barrel aperture. It is made of polypropylene and uncoated. The proximal end of the plunger is flat to allow the device user to apply uniform pressure to the plunger shaft, thereby initiating the plunger into the syringe barrel.

2. **Barrel:** The Barrel is a single, clear molded plastic hollow barrel made of polypropylene. This is the identical material used to manufacture the barrel of the predicate device. The distal end of the barrel possesses an integrally molded syringe tip. The barrel is marked on the exterior with non-toxic, biocompatible ink to create gradient volume graduation markings. The barrel is translucent to allow visualization of fluid contents and volume. The barrel is designed at an appropriate length to accommodate the nominal volume of each syringe size as labeled.

3. **Gasket:** The gasket is attached to the distal end of the syringe plunger in an o-ring orientation. It is attached to the plunger via a mechanical interference fit. The purpose of the gasket is to engage the syringe barrel to form a low-pressure seal, which is impervious to fluids.

4. **Tip cap:** The tip cap is an ENFit compatible closure cap for the tip of the syringe. The syringe tip cap is designed to be compatible with the ENFit female syringe tip of the syringe. The syringe tip cap is made of polypropylene and purple colorant.

No.	Parts & Accessories	Material	Material Specification	Patient Contact (Direct /Indirect)?
1	Barrel	Polypropylene	R370Y	Indirect
2	Plunger	Polypropylene	R370Y	Indirect
3	Gasket	synthetic rubber	/	Indirect
4	Tip Cap	Polypropylene	R370Y	Indirect
5	Barrel Lubricant	Medical highly activated silicone	/	Indirect
6	Volume Graduation Ink	Black ink	PPEC-706	Indirect
7	Colorant	purple	2700071(purple)	Indirect

The subject device may indirectly contact the patients, contact duration ≤24 hr.

Intended Use / Indications for Use

The device is indicated for use as a dispenser, measuring device, and 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) to in all age groups.

Comparison of Technological Characteristics with the Predicate Device

Features	Proposed Device	Predicate Device	Comments
Device	Enteral Feeding Syringes with ENFit Connector (10ml,60ml control ring)	Oral/Enteral Syringes with ENFit connector (12 mL to 100 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® Connector (0.5 mL to 6 mL)	N/A
Manufacturer	Jiangsu Shenli Medical Production Co., Ltd	NeoMed, Inc.	N/A
510(k)	N/A	K161039	N/A
Indication for Use	The device is indicated for use as a dispenser, measuring device, and 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) to 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 settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.	Identical
Service Condition	Prescription use	Prescription use	Identical
FDA Classification	Class II, PNR, Enteral Syringes With Enteral Specific Connectors	Class II, PNR, Enteral syringes with enteral specific connectors	Identical
Configuration	Gasket Plunger/Plunger with Control Ring Barrel with ENFit tip Tip Cap	Gasket Plunger Barrel with ENFit tip With or without Tip Cap	Identical
Single-Use	Yes	Yes	Identical
Sterile	sterile	sterile or non-sterile	Identical
Operation Mode	Manual Use	Manual Use	Identical
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Identical
Size	10 mL; 60 mL	0.5 -100 mL	Comment 1

Features	Proposed Device	Predicate Device	Comments
Performance	Complies with: ISO 7886-1 ISO 80369-3	Complies with ISO 7886-1 ISO 80369-3	Identical
Patient-contact component and material			
-Barrel	Polypropylene	Polypropylene	Identical
-Plunger	Polypropylene	Polypropylene (white colorant)	Comment 2
-Gasket	synthetic rubber	Silicone (black colorant)	
-Tip Cap	Polypropylene (Purple colorant)	Polypropylene (Orange colorant)	
- Volume Graduation ink	Black ink	Orange or purple ink	
Barrel lubricant	Medical highly activated silicone	polydimethylsiloxane	
Biocompatibility	Complied with ISO10993-1	Complied with ISO10993-1	Identical
Sterilization	EO	EO	Identical
SAL	10^{-6}	10^{-6}	Identical

Discussions of differences in technological characteristics

Comment 1

The specifications of the proposed device and predicate device are different; however, both of them comply with the same recognized standards. The differences in enteral feeding syringe sizes will not raise new problems on the safety and effectiveness of the proposed device.

Comment 2

The patient-contact components of the proposed device are the same as those of the predicate device. The patient-contacting materials of the proposed device and the predicated device are different. The proposed device and the predicated devices are biocompatible and conform to ISO 10993 series standards. Therefore, the proposed device demonstrates through testing, to be substantially equivalent to the predicate devices.

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that hypodermic safety needle with a syringe and hypodermic safety needle met all requirements of related international standards, including biocompatibility, sterility, and product specifications. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

- ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 80369-3: 2016 Small-bore connectors for liquids and gases in health care 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

  For the finished device, it meets the defined performance requirements through bench testing.

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1. Patient contact classification: indirectly contact the patients, contact duration≤24 h, Limited Contact Duration (≤24h). The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1, the same as the predicate device.

- In Vitro Cytotoxicity (ISO10993-5: 2009)
- Skin Sensitization (ISO10993-10: 2010)
- Intracutaneous Reactivity Test (ISO10993-10: 2010)

All of the pre-determined acceptance criteria were met.

Sterility Information

The devices are EO sterilized. The sterilization validation conducted according to below standards:

- ISO11135-1 Sterilization of health care products - ethylene oxide - part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO11737-1 Sterilization of medical devices-Microbiological methods-Part 1: Determination of the population of microorganisms on the product.
- ISO11737-2 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process.
- ISO 10993-7 Biological evaluation of medical devices - Part 7: Test of Ethylene Oxide Residuals.
- ANSI/AAMI ST72 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing.

Validation method for the sterilization cycle: Half-cycle method

Sterility assurance level (SAL): 10^{-6}

Sterilization residuals: Complies with standards requirement ISO10993-7: Limited exposure devices

10 ml:

EO Residual: 2.6X10-3 mg/device (Limit:4.0mg/device)

ECH Residuals: < 3.0X10-3mg/device (Limit: 9.0mg/device)

60 ml control ring:

EO Residual: 0.016 mg/device (Limit:4.0mg/device)

ECH Residuals: 0.028 mg/device (Limit: 9.0mg/device)

Bioburden test: Overall adjusted average bioburden 10ml: 3.4 cfu/device

60 ml control ring: 3.4 cfu/device.

All of the pre-determined acceptance criteria were met.

Result of Sterility test: 0 Positives

Result of Pyrogenicity test(the rabbit pyrogen test):

Temperature rise:

10ml: 0.21℃, 0.00℃ , 0.03℃

60 ml control ring: 0.09℃, 0.12℃ , 0.07℃

Result of Endotoxin test (Gel-Clot Limit Test)- Less than 0.25 EU/ml

Package and Shelf Life:

We conducted package and shelf life verification test to support the shelf life claim according to the standards noted below:

- AAMI/ANSI/ISO 11137-1:2006/(R) 2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices

- AAMI/ANSI/ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process

- AAMI/ANSI/ISO 11607-1:2006/(R) 2010 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, 3ed.

- ASTM F1929-98 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

- ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM D3078-02 (2008), Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission. (Sterility)

- ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials

The tests were conducted as noted below:

- Product Performance Inspection (Chemical performance and Physical performance)
- Sterile Test
- Vacuum Leak Test
- Dye penetration test
- Agar Contact-Attack Test
- Tensile Seal Strength Test
- Accelerated Aging Test

The test result supports the five year shelf life claim for the subject device from the sterilization date.

All of the pre-determined acceptance criteria were met.

Clinical Test:

No clinical study is included in this submission.

Conclusion Section:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Enteral Feeding Syringes with ENFit connector Model: 10ml, 60ml control ring is as safe, as effective, and performs as well as the legally marketed predicate device the NeoMed, Inc. Oral/Enteral Syringes with ENFit connector (12 mL to 100 mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® Connector (0.5 mL to 6 mL) cleared under K161039.

END