August 17, 2023

Anhui Tiankang Medical Technology Co., Ltd.
Zhang Yong
Management
No. 228, Weiyi Road, Economic Development Zone
Tianchang, Anhui 239300
China

Re: K222772
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: July 10, 2023
Received: July 17, 2023

Dear Zhang Yong:

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,

Sivakami Venkatachalam -S

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)*
K222772

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 ofa 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.

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510(k) summary

I Submitter

Device submitter: Anhui Tiankang Medical Technology Co., Ltd.
No.228, Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China.

Contact person:
Name: Zhang yong
Title: Management representative
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II Device

Trade Name of Device: Oral/Enteral Syringe with ENFit connector
Common Name: Enteral Syringes With Enteral Specific Connectors
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product code: PNR
Review Panel: Gastroenterology/Urology

III Predicate Device 1

Trade name:	Oral/Enteral Syringe with ENFit connector
Regulation name:	Gastrointestinal tube and accessories
Classification:	Class II
Product Code:	PNR
Premarket Notification:	K211025
Manufacturer:	Ningbo Tianyi Medical Appliance Co., Ltd.

IV Device description

The Oral/Enteral Syringe with ENFit connector is a disposable enteral feeding syringe provided in a variety of sizes from 0.5ml to 60ml. The Oral/Enteral Syringe with ENFit connector consists of plunger, gasket/piston, barrel with ENFit connector, and used to deliver fluids into the body orally or connected 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.

V 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.

VI Comparison of technological characteristics with the predicate devices

The Oral/Enteral Syringe with ENFit connector has the same intended use, technology, design and biocompatibility is either identical or substantially equivalent to existing legally marketed predicate devices. The comparison between the subject device and the predicate devices are listed in below tables:

Table 6-1 Substantial Equivalence Discussion- Oral/Enteral Syringe with ENFit connector

Device feature	Subject Device	Predicate Device K211025	Comment
Product	Oral/Enteral Syringe with ENFit connector	Oral/Enteral Syringe with ENFit connector	/
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 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.	Same
Configuration	Piston/Gasket; Plunger;	Piston; Plunger;	Difference Comment 1

Device feature	Subject Device	Predicate Device K211025	Comment
	Barrel with ENFit connector; Tip cap	Barrel with ENFit connector; Tip cap	
Single Use	Single Use	Single Use	Same
Product Size (nominal volumes)	TKESNC001, TKESNC002, TKESNC003, TKESNC004: 0.5ml, 1ml, 2.5ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml,30ml , 35ml, 60ml. TKESNC005: 0.5ml, 1ml, 2.5ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml, 30ml,35ml , 60ml.	Low dose tip ENFit syringe: 0.5ml, 1ml, 3ml, 6ml; Standard ENFit syringe: 12ml, 20ml, 35ml, 60ml;	Difference Comment 2
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
Materials	Barrel: Polypropylene (PP), Polypropylene (PP) and Amber Pigment; Plunger: Polypropylene (PP) and White Pigment, Polypropylene (PP) and Purple Pigment; Gasket: S1Si; Piston: Polyisoprene Rubber Tip Cap: PP and Purple Pigment, PP and Orange Pigment, PP and White Pigment;	Barrel: Polypropylene (PP) Plunger: Polypropylene (PP) and white pigment Piston: Silicone rubber Tip Cap: Polypropylene (PP) and Orange pigment or polypropylene (PP) and purple pigment	Difference Comment 3
Biocompatibility	No Cytotoxicity; No Irritation; No Sensitization;	No Cytotoxicity; No Irritation; No Sensitization;	Same
Sterile	Sterile	Sterile or non-sterile	Same
Sterile Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same

Difference comment 1

The Gasket of the subject device is not covered by the predicate device, but the Oral/Enteral Syringe with ENFit connector of the structure has passed the verification of ISO 80369-3, ISO 80369-20 and ISO 7886-1 standard tests, and the results meet the

requirements. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Difference comment 2

The product size for subject device is different from predicate device. The subject device includes 12 sizes, 0.5ml, 1ml, 2.5ml/3ml, 5ml/6ml, 10ml/12ml, 20ml, 30ml，35ml, 60ml all of which are covered by predicative device. but after the test of product performance, the safety and effectiveness of the product have been verified. 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.

Difference comment 3

subject device is different from predicate device in material, but the main material of the device is PP. 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.

VII Performance data

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

Biocompatibility testing

Biocompatibility of the Oral/Enteral Syringe with ENFit connector was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "Surface medical device–mucosal membrane" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended：

In Vitro Cytotoxicity Test	ISO 10993-5: 2009
Intracutaneous Reactivity Test	ISO 10993-10: 2010
Skin Sensitization Test	ISO 10993-10: 2010

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters.

The testing is performed according to the following standards:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008

The shelf life of three years is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.

Package integrity testing was conducted on the final, packaged, and sterile devices after environmental conditioning and simulated transportation. All packaging deemed

acceptable for protection of product and sterility maintenance.

The testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Blue Dye Penetration	ASTM F 1929-2015
Seal Integrity (Visual Inspection)	ASTM F 1886/ F 1886M-16

Performance testing

Testing Name	standards	No.
report of PP 5090T	ASTM D638-22，ASTM D790-17 Procedure A	SHMR221101124301
dose accuracy testing	ISO7886-1	1888-0009
Performance report	ISO 80369-3:2016	QDHL2210015086MD

Performance testing is performed according to the following standards:

- ISO 7886-1:2017: Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
- ISO 80369-1:2018: Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- 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

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The Oral/Enteral Syringe with ENFit connector is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.