April 28, 2021

Ningbo Tianyi Medical Appliance Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K210621
Trade/Device Name: Oral/Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: PNR
Dated: February 25, 2021
Received: March 2, 2021

Dear Diana Hong:

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,

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)*

K210621

Device Name
Oral/Enteral Syringe

Indications for Use *(Describe)*

The device is indicated 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.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K210621

1. Date of Preparation: 04/21/2021

2. Sponsor Identification

Ningbo Tianyi Medical Appliance Co., Ltd.
No.788, Mozhi North Road, Tourism Resort, Dongqian Lake, 315121 Ningbo, PEOPLE'S REPUBLIC OF CHINA

Establishment Registration Number: Not registered

Contact Person: Wenyu Zhang
Position: Regulatory Affair Manager
Tel: +86-574-55011007
Fax: +86-574-55011007
Email: vincent.zhang@tianyinb.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Oral/Enteral Syringe
Common Name: Enteral Feeding Syringe

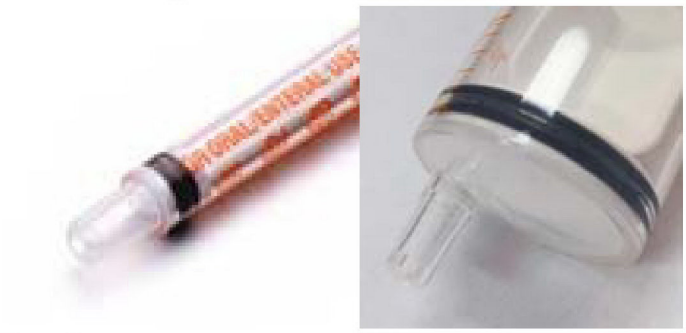
Regulatory Information

Classification Name: Gastrointestinal tube and accessories;
Classification: II;
Product Code: PNR;
Regulation Number: 21CFR 876.5980
Review Panel: Gastroenterology/Urology;

Indication for Use:
The device is indicated 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.

Device Description
The proposed device is a disposable enteral feeding syringe provided in a variety of sizes from 0.5ml to 60ml. The enteral feeding syringe consists of plunger, piston, barrel and tip cap, and used to deliver fluids into the body orally or connected to an enteral access device with male tapered connector. Please refer to Figure 1.

Figure 1 Illustration of Tapered Tip



There are 2 types of the syringe:
Side connector tapered syringe and central connector tapered syringe. The sizes of the central connector tapered syringe range from 0.5ml to 3ml; and side connector tapered syringe range from 6ml to 60ml.

The proposed syringe is sterile or non-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 life of three years.

5. Identification of Predicate Device

Primary Predicate Device
510(k) Number: K192179
Trade Name: Oral/Enteral Syringe

Secondary Predicate Device
510(k) Number: K122373
Product Name: NeoMed Oral/Enteral Syringe (0.5ml to 100ml)

6. 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 test results demonstrated that the proposed device complies with 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 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in 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 14971:2007 Medical Devices-Application of Risk Management to Medical Devices;
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;

Physical, Mechanical, Chemical testing listed in following table were performed on the proposed device. The test results show that the device meets the requirements of related standards.

Item	Standard
General requirements	Clause 5 of ISO 7886-1:2017
Extraneous matter	Clause 6 of ISO 7886-1:2017
Lubricant	Clause 7 of ISO 7886-1;2017
Tolerance on graduated capacity	Clause 8 of ISO 7886-1:2017
Graduated scale	Clause 9 of ISO 7886-1:2017

Barrel	Clause 10 of ISO 7886-1:2017
Piston/ plunger assembly	Clause 11 of ISO 7886-1:2017
Nozzle	Clause 12 of ISO 7886-1:2017
Performance	Clause 13 of ISO 7886-1:2017

Item	Standard
Fluid leakage	Clause 6.1 of ISO 80369-3:2016
Stress cracking	Clause 6.2 of ISO 80369-3:2016
Resistance to separation form axial load	Clause 6.3 of ISO 80369-7:2016
Disconnection by unscrewing	Clause 6.6 of ISO 80369-7:2016

Sterile barrier packaging testing were performed on the proposed device, which include seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and shelf life testing listed in following table were performed on the proposed device. EO ECH residue did not exceed the limit of ISO 10993-7. Shelf life test result showed that the device can maintain its performance during the claimed shelf life.

Item	Standard
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing

The contact level of the proposed device is mucosal membrane, indirect, and the contact duration is limited contact (<24 hours). The proposed device was evaluated for the following tests. The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device.

- Cytotoxicity,
- Sensitization,
- Irritation,

Connector Incompatibility

A connector incompatibility test was performed on proposed device according to FDA Guidance,

Guidance for Industry and FDA Staff: Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications, issued on February 11, 2015, ISO 80369-1:2010 and ISO 14971:2007 to evaluate the incompatibility of the proposed device. The results demonstrated that the proposed device, were unable to connect with other device as specified in ISO 80369-1:2010. (Intravenous, hypodermic applications, breathing systems and driving gases, urethral/urinary, ENFit connector, limb cuff inflation, and neuraxial applications device)

Dose Accuracy Test for Syringe

The dose accuracy test of the enteral syringe is carried out by simulating clinical conditions, the test results show that enteral syringes are accurate to ±10% when the syringe is filled with a minimum dose of 20% of the overall syringe capacity.

Dimensional Verification of Tapered Tip

The tapered tip was dimensional tested, and the test results show that the tip dimensional meets the acceptance standard.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technology Characteristics

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Primary Predicate Device K192179	Secondary Predicate Device K122373	Remark
Product name	Oral/Enteral Syringe	Oral/Enteral Syringe	NeoMed Oral/Enteral Syringe (0.5 mL to 100mL)	/
Product Code	PNR	PNR	FMF	Different
Regulation Number	21CFR 876.5980	21CFR 876.5980	21CFR 880.5560	Different
Class	II	II	II	Same
Indications for Use	The device is indicated 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 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.	The device is indicated for use as a dispenser, a measuring device and an oral fluid transfer device. It is used to inject fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.	Different
Configuration	Piston; Plunger; Barrel with tapered connector; Tip cap	Barrel; Plunger (Rubber Stopper or Rubber Pad); Piston	Syringe Gasket; Syringe Plunger; Syringe Barrel with tapered connector; Syringe Tip; Syringe Cap;	Different
Product Size (nominal volumes)	0.5ml, 1ml, 3ml, 6ml, 12ml, 20ml, 35ml, 60ml	1ml, 3ml, 5ml, 10ml, 20ml, 60ml	0.5ml to 100ml	Different

Product Performance	Complied with: ISO 7886-1 ISO 80369-1;		Complied with: ISO 7886-1; ISO 80369-3; ISO 80369-20;	Complied with: ISO 7886 ISO 80369-1	Different
Material	Barrel	Polypropylene (PP)	Polypropylene (PP)	Unknown	Different
	Plunger	Polypropylene (PP) and white pigment	Polypropylene (PP) and purple pigment		
	Piston	Silicone rubber	Isoprene rubber or silicone rubber		
	Tip Cap	Polypropylene (PP) and Orange pigment Or polypropylene (PP) and purple pigment	/		
Biocompatibility	Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Conform with ISO 10993	Different
	Skin Irritation	No Irritation	No Irritation		
	Sensitization	No Sensitization	No Sensitization		
Sterile	Sterile or non-sterile		Sterile	Sterile	Different
Sterile Method	EO Sterilized		EO Sterilized	EO Sterilized	Same
SAL	10^{-6}		10^{-6}	10^{-6}	Same
Single Use	Single Use		Single Use	Single Use	Same

Different 1- Regulation Number and Product Code

The regulation number and product code of the proposed device and primary predicate device are same, but regulation number and product code of the proposed device and secondary predicate device are difference.

The product code and the regulation number are different because the PNR code was assigned for the Oral/Enteral Syringe by the FDA in recent years. The secondary predicate device was the device that

cleared in 2012, so it was classified under the FMF code. This caused the difference between the product code and the regulatory number of the proposed device and secondary predicate device. This difference between the product code and the regulatory number will not affect the safety and effectiveness.

Different 2- Indication for Use

The indication for use of the proposed device and primary predicate device are same, with only slightly different in the verbal descriptions. The indication for use of the proposed device and secondary predicate device are not exactly the same. The proposed devices and secondary predicate device are indicated for use as a dispenser, a measuring device and an oral fluid transfer device. However, the applicable people of the proposed devices and primary predicative device are same, and the applicable people of the secondary predicate device are neonatal and small pediatric patients. This product is only for delivering liquids to the human body, so different applicable people will not affect the intended use of the product. Now, many oral/enteral syringe that have been marketed are suitable for people of all ages groups.

The use environment of the proposed devices and primary predicative device are same, and the indication for use of the secondary predicate device does not clearly state the use environment. Many of the oral/enteral syringe that have been marketed for indication for use claim that the product can be used in clinical or home care settings. In addition, laypersons are required to use under the supervision of medical practitioners in the indication for use.

In summary, this difference does not raise new safety and effectiveness issues for the device.

Different 3- Configuration

The primary predicate device has not tip cap, which is used to prevent fluid loss and contamination of contents until ready for use and seal the device after using. This difference does not affect intended use. The configuration of the proposed device and secondary predicate device are exactly the same, but the name is different. The secondary predicate device used the tip as a component, but the design of the tip of the proposed device and the secondary predicate device is exactly the same. Therefore, different configuration names do not raise new safety and effectiveness issues for the device.

Different 4 - Product Size

The product size for proposed device is different from primary predicate device and secondary predicate device. The proposed device includes 8 sizes, 0.5 ml, 1ml, 3ml, 6ml, 12ml, 20ml, 35ml, 60ml, all of which are covered by secondary predicate device and the product size is similar to the primary predicate device. 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.

Different 5- Product Performance

The product performance of proposed device and secondary predicate device are same, and the biocompatibility of proposed device and primary predicate device are similar. ISO 80369-1 is a general standard. Therefore, this difference does not raise new safety and effectiveness issues for the device.

Different 6- Material

The material for proposed device is different from primary predicate device and the material for the secondary predicate device is unknown. 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.

Different 7- Biocompatibility

The biocompatibility of proposed device and primary predicate device are same, and the biocompatibility of proposed device and secondary predicate device are different. But both of them comply with standard 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.

Different 8- Sterilization

The proposed device is available in sterile and non-sterile two types. The proposed sterile method is same as the primary predicate device and secondary predicate device. Whether the device is sterilized or not does not affect the indication for use of the device and its performance. Therefore, this difference does not raise new safety and effectiveness issues for the device.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission K210621, the Oral/Enteral Syringe is as safe, as effective, and performs as well as or better than the legally marketed predicative device cleared under K192179 and K122373.