October 11, 2018

Jiangsu Micsafe Medical Technology Co., Ltd
% Helen Nan
General Manager
Wenzhou Cytech Information Service Co., Ltd.
Room302, Building 3, Hangqian Street, Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K181426
Trade/Device Name: Oral/Enteral Syringe (10 mL to 60 mL)
Low Dose Tip Oral/Enteral Syringe (1 mL to 5 mL)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: August 13, 2018
Received: August 13, 2018

Dear Helen Nan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey W. Cooper
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2018.10.11
17:43:14 -04'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K181426

Device Name
Oral/Enteral Syringe(10mL to 60mL)
Low Dose Tip Oral/Enteral Syringe(1mL to 5mL)

Indications for Use *(Describe)*
The subject 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.

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

(As required by 21 CFR 807.92(a))

7.1 Submitter Information

- Company: Jiangsu Micsafe Medical Technology Co., Ltd.
- Address: Xituan Industrial Park, Dafeng District, Yancheng City, Jiangsu Province,224125， China
- Phone: 086-13651929266
- Contact: Tony Yang, General Manager
- Date: May 12, 2018

7.2 Device Information

- Trade/Device Name: Oral/Enteral Syringe(10mL to 60mL)
  Low Dose Tip Oral/Enteral Syringe(1mL to 5mL)
- Model/Size:

Oral/Enteral Syringe:
Type A (Gasket Type): 10ml, 20ml, 60ml
Type B (O-Ring Type): 10ml, 20ml, 60ml
Low Dose Tip Oral/Enteral Syringe:
Type A (Gasket Type): 1ml, 3ml, 5ml
Type B (O-Ring Type): 1ml, 3ml, 5ml

- Common Name: Oral/Enteral Syringes
- Classification: Device: Enteral Syringes With Enteral Specific Connectors
  Regulation Description: Gastrointestinal tube and accessories
  Review Panel: Gastroenterology/Urology
  Product Code: PNR
  Submission Type: 510(k)

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Regulation Number: 876.5980

Device Class: 2

7.3 Predicate Device Information

NeoConnect 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) [510K Number: K161039; submitted by NeoMed, Inc.]

7.4 Device Description

Oral/Enteral Syringe (10 mL to 60 mL) and Low Dose Tip Oral/Enteral Syringe (1 mL to 5 mL) are basically enteral syringes that can also be used for oral uses. There are two different types of models of the syringes, which are Type A and Type B. The Type A syringes of a polypropylene barrel and plunger rod and a synthetic rubber gasket stopper manufactured from polyisoprene. The Type B syringes consist of a polypropylene barrel and plunger rod and a silicone O-ring. The 10 to 60 mL syringes come with the standard female ENFit connector and the 1 to 5 mL syringes come with a female ENFit connector incorporating a low dose tip design.

7.5 Indications for Use

The subject 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.

7.6 Comparison of Technological Characteristics with the Predicate Device

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Comparison Items	Subject Device	Predicate Device (K161039)
Classification & Intended Use		
Classification	PNR & Class 2	PNR & Class 2
Indications for Use	The subject 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 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.

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Technological Characteristics		
Configurations	Barrel	Barrel with ENFit connector
	Transparent/Purple Plunger	Purple Plunger
	Seal	Piston
	No Tip Cap	Tip cap
Size	Oral/Enteral Syringe(10mL to 60mL) And Low Dose Tip Oral/Enteral Syringe(1mL to 5mL)	Oral/Enteral Syringes with ENFit® connector (12 mL to 100mL) and Low Dose Tip Oral/Enteral Syringes with ENFit® connector (0.5 mL to 6 mL)
Sterile	Yes	Yes
Single Use	Yes	Yes
Safety & Effectiveness		
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards
	No Cytoxicity	No Cytoxicity
	No Irritation to Skin	No Irritation to Skin
	No Significant evidence of	No Significant evidence of
	No systemic toxicity	Not applicable.
Performance safety & effectivness	Conforms with the reguirements of ISO 7886-1 and 80369-3	Conforms with the reguirements of ISO 7886-1 and 80369-3

Brief Summary

First, the subject device enjoys identical classification and intended use with the predicate device, which forms the foundation of their substantial equivalence.

Secondly, the subject device boasts similar technological characteristics with the predicate device, such as they are both sterile and for single use. Though they differ slightly in configurations and size, such differences have been further verified by FDA recognized standards - ISO 7886-1 and ISO 80369-3, which ensures that the subject device is safe and effective for usage. Such facts further supports that the two devices are substantial equivalent.

Last but not least, the biocompatibility of both devices has been ensured by relevant ISO 10993 standards, which ensures that the subject device will be as safe for use as the predicate device.

7.7 Discussion of Tests Performed

7.7.1 Clinical Test

Clinical testing was not performed for the subject device as part of the submission.

7.7.2 Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

1) Biocompatibility according to ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity; ANSI AAMI ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization; and ANSI AAMI

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ISO 10993-11:2006/(R)2010 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

2) Performance safety and effectiveness according to ISO 7886-1 Second edition2017-05, Sterile hypodermic syringes for single use - Part 1: Syringes for manual use:

- Cleanliness
- Lubricant
- Limits of extractable metals
- Limits for acidity/alkalinity
- Tolerance on Graduated Capacity
- Graduated Scale
- Dead Space
- Barrel Configuration
- Nozzle Design Verification
- Piston/Plunger Assembly
- Freedom from air and liquid leakage
- Force to operate the piston of the syringe

3) Performance safety and effectiveness according to ISO 80369-3 First Edition 2016-07-01 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications:

- Fluid leakage
- Stress Cracking
- Resistance to separation from axial load
- Resistance to separation from unscrewing
- Resistance to overriding

- Disconnection by unscrewing

4) Additional Performance safety and effectiveness for the Oral/Enteral Syringe(10mL to 60mL) Low Dose Tip Oral/Enteral Syringe(1mL to 5mL):

- Dimensional Verification to ISO 80369-3
- Dimensional Verification of Low Dose Tips
- Dimensional Verification of Syringes
- Risk Management Report
- Dosing Accuracy Testing for Low Dose Tips
- Dosing Accuracy Testing for Oral Administration

7.8 Conclusion

From the above analysis, it is proper to conclude that the subject device will be as safe and effective for usage as the listed predicate device that are already cleared for the U.S. market.