October 5, 2022

Jiangsu Micsafe Medical Technology Co., Ltd
Tony Yang
General Manager
Xituan Industrial Park, Dafeng District
Yancheng, Jiangsu 224125
China

Re: K202570
Trade/Device Name: Insulin Syringe, Insulin Syringe with Safety Retractable
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: MEG, FMF

Dear Tony Yang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 2, 2021. Specifically, FDA is updating this SE Letter because it was unsigned as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact CAPT Alan Stevens, OHT3, at alan.stevens@fda.hhs.gov.

Sincerely,

Alan M. Stevens -S3

CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

July 2, 2021
Jiangsu Micsafe Medical Technology Co., Ltd
Tony Yang
General Manager
Xituan Industrial Park, Dafeng District
Yancheng, Jiangsu 224125
China

Re: K202570
Trade/Device Name: Insulin Syringe, Insulin Syringe with Safety Retractable
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF
Dated: April 10, 2021
Received: June 4, 2021

Dear Tony Yang:

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 Rumi Young
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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)*
K202570

Device Name
Insulin Syringe, Insulin Syringe with Safety Retractable

Indications for Use *(Describe)*
The Insulin Syringe is a sterile, single use and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

The Insulin Syringe with Safety Retractable is a sterile, single use and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

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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K202570 510(k) Summary

(As required by 21 CFR 807.92(a))

Date Prepared: June 30, 2021

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
- Email: info@micsafe.com
- Contact: Tony Yang, General Manager

7.2 Device Information

- Trade/Device Name: Insulin Syringe
  Insulin Syringe with Safety Retractable
- Common Name: Syringe, Antistick Piston Syringe
- Classification:
  Regulation Name: Piston Syringe
  Regulation Number: 21 CFR 880.5860
  Product Code: MEG and FMF
  Device Class: II
  Type of Use: Prescription use only

7.3 Predicate Device Information

U&U Insulin Syringe, U&U Insulin Syringe with Safety Retractable Device

510(k) Number: K152808

7.4 Device Description

(1) Insulin Syringe

This product uses PP, Polyisoprene rubber and SUS304 as the main materials. It consists of barrel, plunger, plunger stopper, needle tube and needle cap.

The product is for single use and provided sterile (EtO). The shelf-life of the product is five-years.

Product Contact Classification:

Externally Communicating, Blood Path and Tissue Contact with prolonged contact duration (>24 h to 30 d).

Models:

	Barrel Item	Specification of Needle	Length of Needle
Insulin Syringe	0.3ml	29G	1/2”
		30G	5/16”
			1/2”
		31G	1/4”
			5/16”
	0.5ml	28G	1/2”
		29G	1/2”
		30G	1/2”
			5/16”
		31G	1/4”
			5/16”
	1ml	27G	1/2”
		28G	1/2”
		29G	1/2”
		30G	1/2”
			5/16”
		31G	1/4”
			5/16”

(2) Insulin Syringe with Safety Retractable

This product uses PP, Polyisoprene rubber and SUS304 as the main materials. It consists of barrel, plunger, plunger stopper, needle tube, safety shield and needle cap.

The product is for single use and provided sterile (EtO). The shelf-life of the product is five-years.

Product Contact Classification:

Externally Communicating, Blood Path and Tissue Contact with prolonged contact duration (>24 h to 30 d).

Models:

	Barrel Item	Specification of Needle	Length of Needle
Insulin Syringe with Safety Retractable	0.5ml	28G	1/2”
		29G	1/2”

		30G	1/2”
			5/16”
		31G	1/4”
			5/16”
	1ml	27G	1/2”
		28G	1/2”
		29G	1/2”
		30G	1/2”
			5/16”
		31G	1/4”
			5/16”

7.5 Indications for Use

(1) Insulin Syringe

The Insulin Syringe is a sterile, single use and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

(2) Insulin Syringe with Safety Retractable

The Insulin Syringe with Safety Retractable is a sterile, single use and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

7.6 Comparison of Technological Characteristics with the Predicate Device

(1) Insulin Syringe

Comparison Item	**Subject Device (K20257)**	**Predicate Device (K152808)**	**Remark**
Identification	Insulin Syringe	U&U Insulin Syringe	
Classification	Product Code: MEG and FMF Class: II	Product Code: MEG and FMF Class: II	Same
Indications for Use	Indicated: The Insulin Syringe is a sterile, single use and non-reusable, insulin syringe intended for injection of U-100	Indicated: The U&U insulin syringe is a sterile, single use, disposable and non-reusable, insulin syringe intended for	Same

	insulin into the body.	injection of U-100 insulin into the body.	
Configuration	Needle Cap (PP)	Needle Sheath (PP)	Same
	Needle Tube (SUS304)	Needle (Stainless Steel)	Same
	Plunger Stopper (Polyisoprene Rubber)	Piston (TPE)	Different (Comment #1)
	Barrel (PP)	Barrel (PP)	Same
	Plunger (PP)	Plunger (PP)	Same
Size	0.3cc/ml Needle 29G to 31G 0.5cc/ml Needle 28G to 31G 1cc/ml Needle 27G to 31G	0.3cc/ml Needle 27G to 31G 0.5cc/ml Needle 27G to 31G 1cc/ml Needle 27G to 31G	Different (Comment #2)
Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards	Same
	No cytotoxicity	No cytotoxicity	Same
	No irritation to skin	No irritation to skin	Same
	No significant evidence of sterilization	No significant evidence of sterilization	Same
	No systemic toxicity	No systemic toxicity	Same
	No hemolysis	No hemolysis	Same
	No pyrogen	No pyrogen	Same
Performance Safety & Effectiveness	Conforms with the requirements of ISO 7864 and ISO 8537	Conforms with the requirements of ISO 7864 and ISO 8537	Same

Brief Summary

The subject device has identical classification with the predicate device and boasts the same indications for use with the predicate device.

The two devices enjoy similar technological characteristics, such as they are both sterile and for single use. Though they differ slightly in configuration and sizes, such differences have been further verified by FDA recognized standards – ISO 7864 and ISO 8537, which ensures that the subject device is safe and effective for usage. Such facts further support that the two devices are substantial equivalent.

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.

Comment #1

The difference between subject device and predicate device is the materials of plunger stopper. However, the biocompatibility test for the subject device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantial equivalence on safety and effectiveness.

Comment #2

The needle gauge and length of between the subjective device and predicate device is different. However, the difference is just in dimension. Different gauge and length device will be selected by the end user. This difference does not affect raise new or different questions of safety or effectiveness.

(2) Insulin Syringe with Safety Retractable

Comparison Item	**Subject Device (K202570)**	**Predicate Device (K152808)**	**Remark**
Identification	Insulin Syringe with Safety Retractable	U&U Insulin Syringe with Safety Retractable Device –	
Classification	Product Code: MEG and FMF Class: II	Product Code: MEG and FMF Class: II	Same
Indications for Use	Indicated: The Insulin Syringe with Safety Retractable is a sterile, single use and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	Indicated: The U&U Insulin Syringe with Safety Retractable Device a sterile, single use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	Same

Materials	Needle Cap (PP)	Needle Sheath (PP)	Same
	Needle Tube (SUS304)	Needle (Stainless Steel)	Same
	Plunger Stopper (Polyisoprene Rubber)	Piston (TPE)	Different (Comment #1)
	Barrel (PP)	Barrel (PP)	Same
	Safety-shield (PP)	Needle Sheath (PP)	Same
	Plunger (PP)	Plunger (PP)	Same
Size	0.5cc/ml Needle 28G to 31G 1cc/ml Needle 27G to 31G	1cc/ml Needle 27G to 31G	Different (Comment #2)
Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Safety feature	Manual retraction It is achieved by pushing the safety device and then rotating it.	Manual retraction It is achieved by pushing the safety device and then rotating it.	Same
Safety Feature Performance	In-Safe mode force: not be more than 5N	Test value:3.45-4.45N	Same
	Resist force: 60s with 20N weights, and the protective device shall not be opened.	Test value:＞20N/60s	Same
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards	Same
	No cytotoxicity	No cytotoxicity	Same
	No irritation to skin	No irritation to skin	Same
	No significant evidence of sterilization	No significant evidence of sterilization	Same
	No systemic toxicity	No systemic toxicity	Same
	No hemolysis	No hemolysis	Same
	No pyrogen	No pyrogen	Same
Performance Safety & Effectiveness	Conforms with the requirements of ISO 7864 and ISO 8537	Conforms with the requirements of ISO 7864 and ISO 8537	Same

Brief Summary

The subject device has identical classification with the predicate device and boasts the same indications for use with the predicate device.

The two devices have similar technological characteristics, such as they are both sterile and for

single use. Though they differ slightly in configuration and sizes, such differences have been further verified by FDA recognized standards – ISO 7864 and ISO 8537, which ensures that the subject device is safe and effective for usage. Such facts further support that the two devices are substantially equivalent.

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.

Comment #1

The difference between subject device and predicate device is the materials of plunger stopper. However, the biocompatibility test for the subject device has been tested and the results comply with the requirements of ISO 10993. Therefore, this difference is not determined to affect substantial equivalence on safety and effectiveness.

Comment #2

The needle gauge and length between the subject device and predicate device is different. However, the difference is just in dimension. These differences were assessed by performance testing, and the difference does not raise new or different questions of safety or effectiveness.

7.7 Discussion of Test Performed

7.7.1 Clinical Tests

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;
- ISO 10993-11: Third Edition 2017-09, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity;

- ISO 10993-4: Third Edition 2017-04. Biological Evaluation Of Medical Devices - Part 4: Selection Of Tests For Interactions With Blood;
- ASTM F756-17, Standard Practice For Assessment Of Hemolytic Properties Of Materials.

(2) Performance safety and effectiveness according to ISO 7864 Fourth Edition 2016-08-01, Sterile Hypodermic Needles For Single Use Requirements And Test Methods:

- Cleanliness
- Limits for acidity or alkalinity
- Limits for extractable metals
- Needle cap
- Tolerances on length
- Freedom from defects
- Lubricant
- Needle point
- Bond between hub and needle tube
- Patency of lumen
- Sharps injury protection

(3) Performance safety and effectiveness according to ISO 8537 Third Edition 2016-03-15, Sterile Single-use Syringes, With Or Without Needle, For Insulin:

- Colour coding
- Limits for acidity or alkalinity
- Limits for extractable metals
- Lubrication of syringes
- Lubrication of needle tube
- Barrel and plunger stopper
- Finger grips
- Fit of plunger stopper in barrel
- Position of nozzle on end of barrel
- Needle tubing for syringe types 5, 6,7, and 8

- Bond between hub and needle tube
- Dead space
- Freedom from leakage at needle
- Freedom from leakage past plunger stopper

(4) Performance safety and effectiveness according to ISO 9626 Second Edition 2016-08-01, Stainless Steel Needle Tubing for The Manufacture of Medical Devices - Requirements and Test Methods:

- Dimensions
- Stiffness
- Resistance to breakage
- Resistance to corrosion

(5) Particulate matter testing per USP <788>, Method 1

(6) ETO residuals ISO 10993-7:2008

(7) Packaging and Shelf life testing per ASTM D4169-16, ASTM F1929-15:1998
ASTM F88:2009

(8) Additional performance safety and effectiveness for Insulin Syringe/ Insulin Syringe with Safety Retractable:

- Risk Management Report
- Sharps Injury Protection Test Report to ISO 23908 First Edition 2011-06-11

7.8 Conclusion

Based on the comparison and analysis above and the performance testing conducted, the subject device is determined to be Substantiality Equivalent (SE) to the predicate device.