August 26, 2021

Guangdong Antmed Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K210991
Trade/Device Name: Disposable Sterile Syringe, Disposable Sterile Syringe with Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: July 23, 2021
Received: July 30, 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,

Alan M. Stevens -S3

CAPT Alan M. Stevens
Assistant Director
Injection Devices Team
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
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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)*
K210991

Device Name
Disposable Sterile Syringe with Needle
Disposable Sterile Syringe

Indications for Use *(Describe)*
The Disposable Sterile Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.

The Disposable Sterile Syringe is a sterile luer lock syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K210991 510(k) Summary

**Date of Preparation**: August 25, 2021

| | |
|---|---|
| **Sponsor Name:** | Guangdong Antmed Co., Ltd. |
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| **Designated Correspondent** | Ms. Diana Hong (Primary Contact Person)<br>Ms. Tingting Su (Alternative Contact Person) |
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## Identification of Proposed Device

Trade Name: Disposable Sterile Syringe with Needle, Disposable Sterile Syringe
Classification Name: Piston Syringe
Device Class: II
Product Code: FMF
Secondary Product Code: FMI
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital

## Identification of Predicate Device

510(k) Number: K072739
Product Name: Sterile Hypodermic Syringe for single use (used as predicate device)
Sterile Insulin Syringe for single use
Retractable Auto-Disable Syringe for single use
Sterile Hypodermic Needle for single use

**Indications for Use:**

The Disposable Sterile Syringe with Needle is intended for use in the aspiration and injection of fluids for medical purpose.

The Disposable Sterile Syringe is a sterile luer lock syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.

**Device Description**

The proposed devices are provided in two types of configurations:

i. a disposable sterile syringe with sterile hypodermic needle contained in a blister packaging made of PP/PE composite film and coated paper sealed by hot sealing
ii. a disposable sterile syringe contained in a blister packaging made of PP/PE composite film and coated paper sealed by hot sealing

The disposable sterile syringe with needle is manually operated and intended for single use only, which consists of a needle and a luer lock syringe. The disposable sterile syringe consists of barrel, plunger and piston. The proposed device is available in various combination of syringe volume and needle size.

**Summary of Technology Characteristics**

**Comparison of Disposable Sterile Syringe with Needle**

| ITEM | Proposed Device | Predicate Device<br>K072739 | Remark |
|---|---|---|---|
| Product | Disposable Sterile Syringe with Needle | Sterile Hypodermic Syringe for single use | / |
| Product Code | FMF<br>FMI | FMF<br>FMI<br>MEG | Analysis<br>1A |
| Regulation Number | 21 CRF 880.5860 | 21 CRF 880.5860 | Same |
| Class | Class II | Class II | Same |
| Indication for Use | The Disposable Sterile Syringe with Needle is and intended for use in the aspiration and injection of fluids for medical purpose. | The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. | Analysis 2 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Condition of Use | | Prescription (Rx) Use only | | Prescription (Rx) Use only | | Same |
| Configuration | | Syringe | Barrel (luer lock) | Syringe | Barrel (luer lock/luer slip) | Analysis 3 |
| | | | Plunger | | Plunger | |
| | | | Piston | | Piston | |
| | | Needle | Needle hub | Needle | Needle hub | |
| | | | Needle tube | | Needle tube | |
| | | | Needle cap | | Needle cap | |
| Operation Mode | | For manual use only | | For manual use only | | Same |
| Sterilized | | Yes | | Yes | | Same |
| Single Use | | Single Use | | Single Use | | Same |
| Label/Labeling | | Complied with 21 CFR part 801 | | Complied with 21 CFR part 801 | | Same |
| Syringe | Volume | 1ml, 3ml, 5ml, 10ml, 20ml | | Luer Slip: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 100ml<br>Luer Lock: 3ml, 5ml, 10ml, 20ml, 50ml, 100ml | | Analysis 4 |
| | Connector Type | Luer Lock | | | | |
| Needle | Size | 23G, 25G | | 16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G | | Analysis 5 |
| | Length | 0.75"(3/4"), 1", 1.25"(1-1/4"), 1.5"(1-1/2") | | 0.5”(1/2“) - 1.5"(1-1/2") | | |
| Syringe Performance | | Complied with ISO 7886-1:2017 | | Complied with ISO 7886-1:1993 | | Analysis 6A |
| Needle Performance | | Complied with ISO 7864:2016 ISO 9626:2016 ISO 6009:2016 | | Complied with ISO 7864:1993 ISO 9626:1991 ISO 6009:1992 | | |
| Luer Connector Performance | | Complied with ISO 80369-7:2016 | | Complied with ISO 594-1:1986 ISO 594-2:1998 | | Analysis 7 |
| Patient-contact Materials | | | | | | |
| Barrel | | Polypropylene (PP) | | Polypropylene (PP) and Stainless Steel | | Analysis 8 |
| Plunger | | Polypropylene (PP) | | | | |
| Piston | | Polyisoprene | | | | |
| Needle hub | | Polypropylene (PP) | | | | |
| Needle tube | | Stainless Steel SUS 304 | | | | |
| Biocompatibility | | | | | | |

| | | | |
|---|---|---|---|
| Cytotoxicity | No cytotoxicity | No cytotoxicity | Analysis 9 |
| Irritation | No intracutaneous reactivity | No intracutaneous reactivity | |
| Sensitization | No sensitization | No sensitization | |
| Systemic Toxicity | No systemic toxicity | No systemic toxicity | |
| Subacute Toxicity | No Subacute toxicity | / | |
| Hemolysis | No Hemolysis | No Hemolysis | |
| Pyrogen | No Pyrogen | No Pyrogen | |
| Complement Activation | Not show potentials to activate complete system | / | |
| In vivo Thrombogenicity | No thrombogenicity | No thrombogenicity | |
| Sterilization | | | |
| Method | EO Sterilized | EO Sterilized | Same |
| SAL | $10^{-6}$ | $10^{-6}$ | Same |
| Endotoxin Limit | 20 EU per device | 20 EU per device | Same |

**Comparison of Disposable Sterile Syringe**

| ITEM | Proposed Device | Predicate Device K072739 | Remark |
|---|---|---|---|
| Product | Disposable Sterile Syringe | Sterile Hypodermic Syringe for single use | / |
| Product Code | FMF | FMF<br>FMI<br>MEG | Analysis 1B |
| Regulation Number | 21 CRF 880.5860 | 21 CRF 880.5860 | Same |
| Class | Class II | Class II | Same |
| Indication for Use | The Disposable Sterile Syringe is a sterile luer lock syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose. | The Sterile Hypodermic Syringe for Single Use With/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. | Analysis 2 |
| Configuration | Barrel (luer lock) | Barrel (luer lock/luer slip) | Analysis 3 |
| | Plunger | Plunger | |
| | Piston | Piston | |

| | | | | |
|---|---|---|---|---|
| Operation Mode | | For manual use only | For manual use only | Same |
| Sterilized | | Yes | Yes | Same |
| Single Use | | Single Use | Single Use | Same |
| Label/Labeling | | Complied with 21 CFR part 801 | Complied with 21 CFR part 801 | Same |
| Syringe | Volume | 1ml, 3ml, 5ml, 10ml, 20ml | Luer Slip: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 100ml<br>Luer Lock: 3ml, 5ml, 10ml, 20ml, 50ml, 100ml | Analysis 4 |
| | Connector Type | Luer Lock | | |
| Syringe Performance | | Complied with ISO 7886-1:2017 | Complied with ISO 7886-1:1993 | Analysis 6B |
| Luer Connector Performance | | Complied with ISO 80369-7:2016 | Complied with ISO 594-1:1986 ISO 594-2:1998 | Analysis 7 |
| Barrel | | Polypropylene (PP) | Polypropylene (PP) | Analysis 8 |
| Plunger | | Polypropylene (PP) | Polypropylene (PP) | |
| Piston | | Polyisoprene | Rubber | |
| Biocompatibility | | | | |
| Cytotoxicity | | No cytotoxicity | No cytotoxicity | Analysis 9 |
| Irritation | | No intracutaneous reactivity | No intracutaneous reactivity | |
| Sensitization | | No sensitization | No sensitization | |
| Systemic Toxicity | | No systemic toxicity | No systemic toxicity | |
| Subacute toxicity | | No Subacute toxicity | Unknown | |
| Hemolysis | | No Hemolysis | No Hemolysis | |
| Pyrogen | | No Pyrogen | No Pyrogen | |
| Sterilization | | | | |
| Method | | EO Sterilized | EO Sterilized | Same |
| SAL | | $10^{-6}$ | $10^{-6}$ | Same |
| Endotoxin Limit | | 20 EU per device | 20 EU per device | Same |

Analysis 1A -Product Code and Regulation Number

In the submission, the predicate device has syringe with/without needle, Auto-disable syringe with/without needle, insulin syringe with fixed needle and hypodermic needle, with the corresponding product codes as FMF, FMI and MEG. The proposed syringe with needle has product codes as FMF and FMI. The subject device does not include a sharps injury protection feature, which is covered by the predicate device product code MEG. The product code of subject device is included in the codes of predicate device. Based on above analysis, the difference on product code and regulation number will not raise new questions on safety and effectiveness of the proposed device.

Analysis 1B -Product Code and Regulation Number

In the submission, the predicate device has syringe with/without needle, Auto-disable syringe with/without needle, insulin syringe with fixed needle and hypodermic needle, with the corresponding product codes as FMF, FMI and MEG. The proposed disposable sterile syringe has product code as FMF. The subject device does not include a sharps injury protection feature, which is covered by the predicate device product code MEG. The product code of subject device is included in the codes of predicate device. Based on above analysis, the difference on product code and regulation number will not raise new questions on safety and effectiveness of the proposed device.

Analysis 2-Indication for Use

The indication for use of the proposed device and the predicative device differ only in the verbal descriptions, and the actual indication for use of both devices is exactly the same. Both devices are intended for use in the aspiration and injection of fluids for medical purpose. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 3- Configuration

The configuration of the proposed device is similar to the configurations of the predicate device, except for the type of barrel connector. The predicate device has the configuration of barrel with luer lock or luer slip connector while the proposed device has the configuration of barrel with luer lock connector only - which is covered by the predicate device connector type. Based on above analysis, the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Analysis 4-Syringe Volume and Connector Type

The Syringe volume for proposed device is different from the predicate devices. However, this difference is just in dimension. Moreover, the syringe volume of the proposed device is covered by the range of the syringe volume of the predicate device. The predicate device has the configuration of barrel with luer lock or luer slip connector while the proposed device has the configuration of barrel with luer lock connector only which is covered by the predicate device connector type. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 5-Needle Size and Length

The needle size for proposed device is different in dimensions from the predicate device. Moreover, the needle size of the proposed device is included in the range of the needle size of the predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 6A -Syringe Performance and Needle Performance

The proposed and predicate device have been tested in accordance with ISO 7886,7864, 6009 and

9626, and the test results meet the requirements of the standards. Although the version numbers of the standard followed by the predicate devices and the proposed devices are different, the three standards followed by the proposed device are all FDA recognized consensus standards. Therefore, different version numbers of the standard do not raise new questions on safety and effectiveness of the proposed device.

Analysis 6B -Syringe Performance

The proposed and predicate device have been tested in accordance with ISO 7886-1 and the test results meet the requirements of the standards. Although the version numbers of the standard followed by the predicate devices and the proposed devices are different, this standard followed by the proposed device are all FDA recognized consensus standards. Therefore, different version numbers of the standard do not raise new questions on safety and effectiveness of the proposed device.

Analysis 7-Luer Connector Performance

The proposed device and the predicate device follow different luer connector standards - this is because ISO 594-1, ISO 594-2 is replaced by ISO 80369-7 according to current regulations. The test results of the proposed device show that the connector performance meet the requirements of ISO 80369-7. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 8- Patient-contact Materials

Although the patient-contacting materials for the proposed device is different from the predicate device, however, biocompatibility test has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Analysis 9-Biocompatibility

The biocompatibility test items of proposed device are different from predicate device. Since the contact level of the proposed device is blood path, indirect, and the contact duration is prolonged contact (<30 days) therefore, the additional biocompatibility endpoints were also evaluated for the proposed device. The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed device. Therefore, this difference does not raise new safety and effectiveness issues for the device.

**Performance testing (Non-Clinical)**

Non clinical tests were conducted to verify that the proposed device met all design specifications and to demonstrate it is Substantially Equivalent (SE) to the predicate device. The test results

demonstrated that the proposed device complies with the following standards:

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: Test for irritation and skin sensitization.
ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
ISO 10993-4:2017 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
ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials (Sterility)
ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
ISO 9626:2016, Stainless Steel Needle Tubing for The Manufacture of Medical Devices
ISO 6009 – 2016 Hypodermic needles for single use - Color coding for identification
ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
ISO 10993-7:2008 Biological Evaluation of Medical Device-Part 7: Ethylene Oxide Sterilization Residuals
USP<85> Bacterial Endotoxins Test
USP<788> Particulate Matter in Injections

**Sterility, Shipping and Shelf-Life**

The proposed devices are 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.

Sterile barrier packaging testing were performed on the proposed device, which include visual inspection (ASTM F1886/F1886M-16), 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. In addition, after simulation transport of the aging sample, the test result also 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. Endotoxin limit did not exceed 20EU/device. Shelf-life test result showed that the device can maintain its performance during the claimed shelf life.

| Item | Test Method |
|---|---|

| | |
|---|---|
| EO residue | ISO 10993-7:2008 |
| ECH residue | ISO 10993-7:2008 |
| Bacteria Endotoxin Limit | USP <85> |

**Biocompatibility testing**

In accordance with ISO 10993-1, contact level of the proposed device is blood path, indirect, and the contact duration is prolonged contact (<30 days). 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,
Intracutaneous,
Acute Systemic Toxicity,
Subacute Toxicity,
Hemolysis,
Pyrogen,
Complement Activation,
In Vivo Thrombogenicity,
Particulate testing

**Conclusion**

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Disposable Sterile Syringe with Needle and Disposable Sterile Syringe is substantially equivalent to the legally marketed predicative device cleared under K072739 with respect to the indications for use, target populations, treatment method, and technological characteristics.