July 17, 2020

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

Re: K193526
Trade/Device Name: Syringe with safety needle, Safety needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FMF, MEG
Dated: June 5, 2020
Received: June 23, 2020

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,

For CAPT Alan M. Stevens
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193526

Device Name
Syringe with Safety Needle
Safety Needle

Indications for Use *(Describe)*
The Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

The Safety Needle is intended for use with a luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K193526

1. Date of Preparation: 07/17/2020

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
No.23, Huanxi Road, Zhutang Town, Jiangyin City, Jiangsu, 214415, China

Establishment Registration Number: 3005670221

Contact Person: Jianwei Pan
Position: Management Representative
Tel: +86-510-8686 6666-8027
Fax: +86-510-8686 6666-8009
Email:jianwei.pan@cainamed.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (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: Syringe with Safety Needle, Safety Needle
Common Name: Piston syringe and antistick needle

Regulatory Information
Classification Name: Syringe, Piston
Classification: II;
Product Code: FMF;
Regulation Number: 21CFR 880.5860;
Review Panel: General Hospital;

Classification Name: Needle, Hypodermic, Single Lumen
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570;
Review Panel: General Hospital;

Classification Name: Syringe, Antistick
Classification: II;
Product Code: MEG;
Regulation Number: 21 CFR 880. 5860;
Review Panel: General Hospital

5. Identification of Predicate Device and Reference Device

Predicate Device Information:
510(k) Number: K170651
Product Name: Sterile Disposable Syringe with Safety Needle (used as predicate device)
Sterile Disposable Syringe with Needle
Sterile Disposable Syringe
Sterile Disposable Safety Needle (used as predicate device)
Sterile Disposable Needle

Regulatory Information
Classification Name: Syringe, Piston
Classification: II;
Product Code: FMF;
Regulation Number: 21CFR 880.5860;
Review Panel: General Hospital;

Classification Name: Needle, Hypodermic, Single Lumen
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570;
Review Panel: General Hospital;

Classification Name: Syringe, Antistick
Classification: II;
Product Code: MEG;
Regulation Number: 21 CFR 880.5860;
Review Panel: General Hospital;

Reference Device Information:
510(k) Number: K161170
Product Name: BD Eclipse™ Hypodermic Needle

Regulatory Information
Classification Name: Needle, Hypodermic, Single Lumen
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570;
Review Panel: General Hospital;

6. Indications for Use:

The Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

The Safety Needle is intended for use with a luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

7. Device Description

The proposed devices are provided in two types of configurations; one type is a syringe with safety needle contained in a sterility maintenance package, the other is one safety needle contained in a sterility maintenance package.

The Syringe with Safety Needle is available in various combination of syringe volume and needle size. The proposed device is operated manually. The liquid is aspiration into the syringe by pulling the

plunger manually and injected into the body by pushing the plunger manually. When the needle is pulled out from the body, push the safety shield to cover the needle.

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 five years.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison of Syringe with Safety Needle

ITEM	Proposed Device	Predicate Device K170651	Referenced Device K161170	Remark
Product	Syringe with Safety Needle	Sterile Disposable Syringe with Safety Needle	BD Eclipse™ Hypodermic Needle	/
Product Code	FMF FMI MEG	FMF FMI MEG	FMI	Same
Regulation Number	21 CRF 880.5860 21 CRF 880.5570	21 CRF 880.5860 21 CRF 880.5570	21 CRF 880.5570	Same
Class	Class II	Class II	Class II	Same
Indication for Use	The Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	The Sterile Disposable Syringe with Safety Needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental	The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse Hypodermic Needle is compatible for use with standard luer-lock syringes. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated	Same

			needle sticks.		position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	
Configuration	Syringe	Barrel (luer lock)	Syringe	Barrel (luer lock/luer slip)	/	Different
		Plunger		Plunger	/	
		Piston		Piston	/	
	Needle	hub	Needle	hub	hub	
		Needle tube		Needle tube	Needle tube	
		Needle cap		Needle cap	Needle cap	
		Safety shield		Safety shield	Safety shield	
Different-Configuration The configuration of proposed syringe with safety needle is similar as predicate device, considering the needle may become disengaged from the syringe when activating the safety shield for the syringe with luer-slip connector, therefore the proposed syringe with safety needle doesn't have the configuration of barrel with luer-slip connector. We think the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.						
Operation Mode	For manual use only		For manual use only		For manual use only	Same
Sterilized	Yes		Yes		Yes	Same
Single Use	Single Use		Single Use		Single Use	Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Complied with 21 CFR part 801	Same
Syringe	1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml		1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml		/	Different
Needle	Connector Type	Luer Lock	Luer Lock /Luer Slip		/	
	Size	16G,18G,	16G,18G, 19G,		/	Different

		19G, 20G, 21G, 22G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G		
	Length	13mm, 16mm, 20mm, 25mm, 32mm, 38mm	8mm(5/16"), 13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	/	
	Needle hub	Color-coded per ISO 6009	Color-coded per ISO 6009	/	Same

Different- Syringe Volume and Connector Type

The Syringe volume for proposed device is different from the predicate devices. However, this difference is just in dimension. Different volume device will be selected by physician per patient's condition. This difference does not affect intended use. Moreover, the syringe volume of the proposed syringe with safety needle is covered by the range of the syringe volume of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Different-Needle Size and Length

The needle size and length for proposed device is different from the predicate device. However, this difference is just in dimension. Different size and length device will be selected by physician per patient's condition. This difference does not affect intended use. Moreover, the needle length of the proposed syringe with safety needle is included in the range of the needle length of the predicate device. The needle size of the syringe with safety needle is very close to that of the comparison product. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Cytotoxicity	No cytotoxicity	No cytotoxicity	/	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	/	
Sensitization	No skin sensitization	No skin sensitization	/	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	/	
Hemolysis	No Hemolysis	No Hemolysis	/	

Pyrogen	No Pyrogen	No Pyrogen	/	
Method	EO Sterilized	EO Sterilized	/	Same
SAL	10^{-6}	10^{-6}	/	Same
Endotoxin Limit	20 EU per device	20 EU per device	/	Same

Table 2 General Comparison of Safety Needle

ITEM	Proposed Device	Predicate Device K170651	Remark
Product	Safety Needle	Sterile Disposable Safety Needle	/
Product Code	FMI	FMI	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	Same
Class	Class II	Class II	Same
Indication for Use	The Safety Needle is intended for use with luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.	The Sterile Disposable Safety Needle is intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	Same
Configuration	Hub Needle tube Needle cap Safety shield	Hub Needle tube Needle cap Safety shield	Same
Operation Mode	For manual use only	For manual use only	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Connector Type	Luer Lock	Luer Lock /Luer Slip	Different
Needle Gauge	31G, 30G, 29G, 28G, 27G, 26G, 25G, 23G, 22G, 21G, 20G, 19G, 18G, 16G	16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Different
Needle Length	13mm, 16mm, 20mm, 25mm, 32mm, 38mm	8mm(5/16"), 13mm(1/2"), 16mm(5/8"), 20mm(3/4"), 25mm(1"), 32mm(1-1/4"), 38mm(1-1/2")	

Different-Connector type

The connector type of proposed needle is covered by the predicated device. Considering the needle may become disengaged from the syringe when activating the safety shield for the syringe with luer-slip connector, therefore the proposed safety needle is not available in luer-slip connector. Therefore, we think the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Different-Needle Gauge and length

The proposed needle has extra 31G than the predicate device. And the 31G needle is similar the 30G in dimension. The needle gauge and length will be selected by physician per patient's condition. This difference does not affect intended use. Therefore, this difference does not affect substantially equivalence on safety and effectiveness

Needle Hub	Color-coded per ISO 6009	Color-coded per ISO 6009	Same
Safety mechanism	Similar safety shield and same manual activated mechanism.	Similar safety shield and same manual activated mechanism.	Same
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No skin sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

9. 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 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 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 23908:2011 Sharps injury protection - Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- USP<788> Particulate Matter in Injections

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
Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016

Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016

Item	Standard
Surface finish and appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

Item	Standard
Fluid leakage	Clause 6.1 of ISO 80369-7:2016
Sub-atmospheric pressure air leakage	Clause 6.2 of ISO 80369-7:2016
Stress cracking	Clause 6.3 of ISO 80369-7:2016
Resistance to separation form axial load	Clause 6.4 of ISO 80369-7:2016
Resistance to separation form unscrewing	Clause 6.5 of ISO 80369-7:2016
Resistance to overriding	Clause 6.6 of ISO 80369-7:2016

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

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.

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	Standard
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
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 blood path, 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,
- Intracutaneous,
- Acute Systemic Toxicity,
- Hemolysis,
- Pyrogen
- Particulate testing

Simulated Clinical Study

A simulated clinical study was performed on proposed device according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine its safety feature. The results demonstrated that both the test data of the proposed device is very close to the test data of the predicate device.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the legally marketed predicate device