June 14, 2018

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

Re: K172938
Trade/Device Name: Disposable Sterile Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 4, 2018
Received: May 8, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

Alan M. Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001 89211, cn=Alan M. Stevens -S
Date: 2018.06.14 13:35:06 -04'00'

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K172938

Device Name
Disposable Sterile Needle

Indications for Use *(Describe)*
The Disposable Sterile Needle is intended for use with syringes and injection devices for general purpose fluid injection/ aspiration.

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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K172938 510(k) SUMMARY

Submitter:	Jiangsu Caina Medical Co., Ltd. No.23, Huanxi Road, Zhutang Town, Jiangyin, Jiangsu, 214425, China
Application Correspondent:	Ms. Diana Hong General Manager Mid-Link Consulting Co., Ltd P.O. Box 120-119, Shanghai, 200120, China Tel: +86-21-22815850, Fax: 240-238-7587 Email: info@mid-link.net
Preparation Date:	June 13, 2018
Trade Name:	Disposable Sterile Needle
Common or Usual Name:	Needle, Hypodermic, Single Lumen
Regulation Name:	Hypodermic Single Lumen Needle.
Regulation Number:	21 CFR 880.5570
Product Code:	FMI
Device Class:	Class II
Primary Predicate Device:	K072739; Jierui Syringes and Needles Note – K072739 is a bundled 510(k) submission containing a sterile hypodermic needle. K172938 is substantially equivalent to the sterile hypodermic needle component of K072739.

Indications for Use:
The Disposable Sterile Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Device Description:

The Disposable Sterile Needle consists of three components: needle tube, needle hub, and the needle cap. The Disposable Sterile Needle is supplied sterile for single use and has a shelf life of 5 years. The proposed device is available in various combinations of needle gauge, length, wall type and Edges. The hub color of the needle complies with ISO 6009: 2016 - Hypodermic needles for single use — Colour coding for identification. The product specifications are listed in following table.

Gauge	Hub Color	Product specification
33G	Black	33Gx6mm RWxLB
		33Gx6mm RWxSB
		33Gx6mm TWxLB
		33Gx6mm TWxSB
32G	Deep Green	32Gx13mm RWxLB
		32Gx13mm RWxSB
		32Gx13mm TWxLB
		32Gx13mm TWxSB
		32Gx13mm ETWxLB
		32Gx13mm ETWxSB
30G	Yellow	30Gx25mm RWxLB
		30Gx25mm RWxSB
		30Gx25mm TWxLB
		30Gx25mm TWxSB
		30Gx25mm ETWxLB
		30Gx25mm ETWxSB
25G	Orange	25Gx25mm RWxLB
		25Gx25mm RWxSB
		25Gx25mm TWxLB
		25Gx25mm TWxSB

Gauge	Hub Color	Product specification
22G	Black	22Gx25mm RWxLB
		22Gx25mm RWxSB
		22Gx25mm TWxLB
		22Gx25mm TWxSB
		22Gx25mm ETWxLB
		22Gx25mm ETWxSB
		22Gx38mm RWxLB
		22Gx38mm RWxSB
		22Gx38mm TWxLB
		22Gx38mm TWxSB
		22Gx38mm ETWxLB
		22Gx38mm ETWxSB
21G	Deep Green	21Gx38mm RWxLB
		21Gx38mm RWxSB
		21Gx38mm TWxLB
		21Gx38mm TWxSB
		21Gx38mm ETWxLB
		21Gx38mm ETWxSB
20G	Yellow	20Gx38mm RWxLB
		20Gx38mm RWxSB

		25Gx38mm RWxLB				20Gx38mm TWxLB
		25Gx38mm RWxSB				20Gx38mm TWxSB
		25Gx38mm TWxLB				20Gx38mm ETWxLB
		25Gx38mm TWxSB				20Gx38mm ETWxSB
Note： **RW = Regular Wall; TW = Thin Wall; ETW= Extra Thin Wall** **LB=Long Bevel; SB=Short Bevel**				18G	Pink	18Gx50mm RWxLB
						18Gx50mm RWxSB
						18Gx50mm TWxLB
						18Gx50mm TWxSB

Device Comparison of Technology

A technological comparison table is provided below that compares the subject device and predicate device:

Item		**Proposed Device –K172938** **Disposable Sterile Needle**	**Predicate Device - K072739** **Jierui Syringes and Needles: Sterile Hypodermic Needle Component Only**	**Comparison**
Product Code		FMI	FMI	Same
Intended Use		The Disposable Sterile Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	Same
Single Use		Yes	Yes	Same
Sterility Condition		EO Sterilization	EO Sterilization	Same
Material	Needle Tube	304 Stainless Steel	Stainless Steel	Different
	Cap	Polypropylene	Unknown	Different
	Hub	Polypropylene	Unknown	Different
Needle Gauge		18G,20G,21G,22G,25G,30G,32G,33G	16G,18G,19G,20G,21G,22G,23G,24G,25G,26G,27G,29G	Different

Needle Length	6mm, 13mm, 20mm, 25mm, 38mm, 45mm, 50mm	13 mm, 16 mm, 19 mm, 25 mm, 32 mm, 38 mm	Different
Needle Edge/Bevel Angle	Long Bevel: angle 11 ° Short Bevel: angle 17 °	Long bevel Short Bevel	Different
Needle Performance	Complies with ISO 7864: 2016 ISO 9626: 2016	Complies with ISO 7864: 1993 ISO 9626: 1991	Same
Luer Connector Performance	Complies with ISO 594-1:1986 ISO 594-2:1998	Complies with ISO 594-1:1986 ISO 594-2:1998	Same
Needle Hub Color	Complies with ISO 6009: 2016	Complies with ISO 6009: 2016	Same

Substantial Equivalence Discussion

The indications for use and intended use of the hypodermic needle component in the predicate bundled 510(k) K072739, are equivalent to the subject 510(k) device.

The differences between the subject device and the predicate device are the following:

- Needle length
  Although the needle length range of the subject device is larger than needle length range of the predicate device r, the needle length of the subject device meets 4.10.2 Tolerances requirements of ISO 7864. This difference does not raise different questions of safety and effectiveness

- Needle Gauge
  The subject device has 30G, 32G and 33G needle gauges, which are not included in the predicate device. All needle gauges of proposed device meet 5.4 Dimensions requirements of ISO 9626. This difference does not raise different questions of safety and effectiveness

- Edge/Bevel angle
  Although the /bevel angle of the predicate device is unknown, the edge/bevel angle of subject device are listed in the product labeling, and the end user can choose the needle per their preference. This difference does not raise different questions of safety and effectiveness

- Materials
  Although the materials of the subject device are different from those of the predicate device, the subject device has been tested for biocompatibility and meets the biocompatibility requirements of the applicable standards in the ISO 10993 series. This difference does not raise different questions of safety and effectiveness

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.

Performance Testing Summary

Non-clinical tests were conducted to verify that the proposed devices met all design specifications and are substantially equivalent (SE) to the hypodermic needle component of the predicate device. The test results demonstrated that the proposed devices comply with the following standards:

- ISO 7864:2016, Sterile Hypodermic Needles for Single Use
- ISO 6009: 2016 - Hypodermic needles for single use — Colour coding for identification
- ISO 9626:2016, Stainless Steel Needle Tubing for the Manufacture of Medical Devices
- ISO 594-1:1986 Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 1: General Requirements.
- ISO 594-2:1998 Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- USP <85> Bacterial Endotoxins Test
- ISO 11135-1:2007 – Sterilization of Health Care Products- Ethylene Oxide- Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

The Disposable Sterile Needle is supplied sterile for single use and are sterilized by Ethylene Oxide to achieve a SAL of 10-6 and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years. Sterility was validated in accordance with ISO 11135-1:2007. Packaging tests were performed per ASTM F88/F88M-15 and ASTM F1929-15.

The Disposable Sterile Needle has been tested for biocompatibility and meets the biocompatibility requirements of the applicable standards in the ISO 10993 series. The device

was tested to the following biocompatibility endpoints: cytotoxicity, sensitization, irritation sensitivity, acute systemic toxicity, and material mediated pyrogenicity, hemocompatibility.

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

In all testing, the pre-determined acceptance criteria were met.

Substantially Equivalence Conclusion

The subject device has the same intended use and technological characteristics as the predicate device. The performance of the device is supported by non-clinical testing and risk management activities. The Disposable Sterile Needle is Substantially Equivalent (SE) to the Sterile Hypodermic Needle component of the bundled 510(k), Jierui Syringes and Needles, cleared under K072739.