July 20, 2020

Jiangsu Caina Medical Co.,Ltd.
Xinyan Ruan
Quality Engineer
No.23, Huanxi Road, Zhutang Town
Jiangyin, 214415 Cn

Re: K193022
Trade/Device Name: Retractable Safety Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: June 18, 2020
Received: June 22, 2020

Dear Xinyan Ruan:

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 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

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)*

Device Name

Indications for Use *(Describe)*

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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"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."

Tab 2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: **K193022**

1. Date of Preparation: 04/29/2020

2. Sponsor Identification

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

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Retractable Safety Insulin Syringe

Regulatory Information
Classification Name: Syringe, Anitstick
Classification: II
Product Code: MEG
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

Indications for Use Statement:
The Retractable Safety Insulin Syringe is a sterile, single use, disposable and non-reusable, automatically 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.

5. Device Description

The Retractable Safety Insulin Syringe has the same technological characteristics as the Retractable Safety Syringe(manufacture by Jiangsu Caina Medical Co., Ltd.) as cleared in K191490 at date 2019/10/03.The difference between the Retractable Safety Insulin Syringe and the 1ml Retractable Safety Syringe is only the scale.

The Retractable Safety Insulin Syringe works like a conventional insulin syringe except for its ability to retract the contaminated needle inside of the syringe immediately after patient injection. Needle retraction is activated by the syringe user. Because the contaminated needle is automatically withdrawn into the syringe plunge, the syringe user is protected from accidental needle sticks. These accidental needle sticks would occur between removing the needle from the patient and disposing of the syringe in a sharps disposable container.

The Retractable Safety Insulin Syringe is available in various specifications. The proposed device consists of eleven components: (1) plunger, (2) piston, (3) barrel, (4) needle cap, (5) sealing plug, (6) slide bushing, (7) needle tube, (8) spring, (9) plunger lid, (10) barrel barb, (11) hub.

The proposed device is provided sterile. The product is 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.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K152808
Product Name: U&U Insulin Syringe with/without Safety Retractable Device

6. 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 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization

Residuals

- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- USP <151> Pyrogen Test
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- ISO 7864:2016 Sterile hypodermic needles for single use-requirements and test method.
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of the medical devices-requirements and test method
- ISO 8537:2016 Sterile Single-use syringes, with or without needle ,for insulin
- 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

The structure principle, safety function and operation method of the proposed devices are identical with Retractable Safety Syringes(manufacture by Jiangsu Caina Medical Co., Ltd.) as cleared in K191490 at date 2019/10/03.Simulated clinical study was not conducted on proposed device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics with K152808

ITEM	Proposed Device	Predicate Device K152808	Comment
Product code	MEG	MEG and FMF	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same

Class	II	II	Same
Indications for use	The Retractable Safety Insulin Syringe is a sterile, single use, disposable and non-reusable, automatically 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.	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. The U&U insulin syringe is a sterile, single use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.	Same
Configuration	Piston Plunger Barrel Needle Hub Needle Safety feature	Piston Plunger Barrel Needle Hub Needle Safety feature	Same
Sterility condition	EO Sterilized	EO Sterilized	Same
Environment of use	Home or Hospital	Home or Hospital	Same
Safety feature principle	Spring retraction	manual retraction	See Comment 1
Volume	1ml	1ml	Same
Needle gauge	27-31G (0.25mm~0.40mm)	27-31G	Same
Needle length	8mm,10mm,13mm	Unknown	See Comment 2
Single use	Yes	Yes	Same
Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	Same
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Materials	PP, Polysoprene, TPE, Stainless Steel, MABS and	PP,TPE,Stainless Steel,Silicone Oil	See Comment 3

	Polydimethysiloxane		
Performance Testing	Conform to: ISO 7864 ISO 9626 ISO 8537 ISO 23908	Conform to: ISO 7864 ISO 9626 ISO 8537 ISO 23908	Same
Safety Feature Performance	Force to activation: not be more than 25N; test value 10.48-20.91	Test value 10.18-20.45N;	Same
	Force to move plunger: not be less than 70N; test value 83.67-116.97	NA;	Comment 4
	Reuse prevention: It is achieved through the barrel barb and convex point are stuck when the plunger is pushed to the bottom.	Reuse prevention: It is achieved through pulling back the plunger and snapped off.	
	Force to separate plunger lid: not be less than 20N; test value 25.14-32.67	Test value 25.18-32.92N;	Same
Biocompatibility	Cytotoxicity	Conforms to ISO10993 (Part1:Evaluation and testing, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals,Part 10: Tests for irritation and delayed-type hypersensitivity, Part 11: Tests for systemic toxicity)	Same
	Sensitization		
	Irritation		
	Acute systemic toxicity		
	Material mediated pyrogenicity		
	Hemocompatibility		
	Subchronic toxicity		
	Particulate matters		

Comment 1

Differences in safety feature principle between the predicate and subject device were addressed through ISO 23908 Safety Feature Performance Test.The safety feature principle of subject devicer is identical with Retractable Safety Syringes(manufacture by Jiangsu Caina Medical Co., Ltd.) as cleared in K191490 at date 2019/10/03.

Comment 2

Differences in needle length between the predicate and subject device were addressed through ISO 8537 performance testing.

Comment 3

Differences in materials between the predicate and subject device were addressed through Biocompatibility Statement and copy of test report.

Comment 4

Differences in reuse prevention, for the predicate device this is achieved through pulling back the plunger and snapped off, for the proposed device,a convex point is designed on the plunger and a barrel barb is designed in the barrel. When the plunger is pushed to the bottom, the barrel barb and convex point are stuck, the plunger can not be re-moved to prevent reuse. At the same time, the front end of the slide bushing opens the barrel to release the needle hub and activate the safety function. Under the action of the spring, the needle hub falls back into the plunger, and the needle tube is shielded inside the plunger. Force to re-move plunger have be tested in Safety Feature Performance Test Report, which is more than 70N. Proposed Device and Predicate Device are different designs, however performance demonstrated the differences do not raise any new safety concerns.

9. Substantially Equivalent (SE) Conclusion

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