DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 2, 2015

Jiangyin Caina Technology Company Incorporated
c/o Mr. Mark Job
Regulatory Technology Services, Inc.
1394 25th Street, NW
Buffalo, MN 55313

Re: K151949
Trade/Device Name: Disposable Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 14, 2015
Received: September 18, 2015

Dear Mr. Job:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151949

Device Name

Disposable Insulin Syringe

Indications for Use *(Describe)*

The disposable insulin syringe is intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

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."

Exhibit 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: K151949

1. Date of Preparation: 9/8/2015

2. Sponsor Identification

Jiangyin Caina Technology Co., Ltd.
No.2, Taifu Road, Huashi Town, Jiangyin, Jiangsu, 214421, China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Insulin Syringe
Common Name: Insulin syringe with needle

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

Intended Use Statement:

The disposable insulin syringe is intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.

Device Description

The Disposable Insulin Syringes are provided sterile, single use.

For the Disposable Insulin Syringes, they consist of six components: (1) orange needle cap (2) needle (3) piston (4) plunger (5) barrel (6) orange protective end cap. The materials for all components are listed in Table 1 Component material list.

Table 1 Component material list

Component	Material
Protective end cap	PE (polyethylene)
Plunger	PP (polypropylene)
Piston	Polysoprene
Barrel	PP (polypropylene)
Needle cap	PE (polyethylene)
Needle	304 Stainless steel
Lubricant	Polydimethylsiloxane

The Disposable Insulin Syringes are available in different combination of syringe volumes and needle sizes. The range of syringe volume, needle gauge and needle length are listed in Table 2 syringe and needle specification.

Table 2 the range of syringe volume, needle gauge and needle length

Syringe volume	Needle gauge	Available Needle length
0.3ml	28G	3/8″, 1/2″, 5/16″or 5/8″
0.5ml	29G	3/8″, 1/2″, 5/16″or 5/8″
1ml	30G	3/8″, 1/2″, 5/16″or 5/8″

5. Identification of Predicate Device

510(k) Number: K072739
Product Name: Sterile Insulin Syringe for single use with fixed needle
Manufacturer: ShanDong Weigao Group Medical Polymer Products Co., Ltd

6. Identification of Reference Device

510(k) Number: K113091
Product Name: Syringe and Needles
Manufacturer: Jiangyin Caina Technology Co., Ltd

7. 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 9626:1991+AMENDMENT 1 2001 Stainless steel needle tubing for the manufacture of medical devices;
- ISO 8537: 2007 Sterile single-use syringes, with or without needle, for insulin;
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F 88/F88M-09 Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/F1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages;
- USP37-NF32 <85> Bacterial Endotoxins Limit.
- ISO 11737-2:2009 Sterilization of medical devices- Microbiological methods- Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process
- 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.
- ASTM F1886/F1886M-09 (Reapproved 2013), Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection. (Sterility)
- ASTM F1929-12, Standard Test Method For Detecting Seal Leaks In Porous Medical

Packaging By Dye Penetration. (Sterility)

Biocompatibility conclusion:

The patient-contact materials of product components of the proposed device, Disposable Insulin Syringe, are identical to the patient-materials of product components of the legally marketed device, Syringes and Needles, as it was cleared in K113091, in 10/28/2011, which is also manufactured by Jiangyin Caina Technology Co., Ltd.

Although the proposed devices are insulin syringe, the previous devices are disposable syringe, however, their manufacturing process, including sterilization process, are exactly the same, and the intended application scope are both for hypodermically injection of fluid to human body.

The necessary tests for biocompatibility testing including Cytotoxicity, Sensitization, Irritation on Intracutaneous Reactivity, System Toxcity (Acute) and Haemo-compatiblity have been provided in K113091 Submission. And the biocompatibility test results can demonstrate the compatibility of all of the patient-contact materials of the proposed device meets the requirements of Biocompatibility.

Shelf life Conclusion:

A maximum shelf life of 5 years has been assigned to the proposed device, when stored unopened at ambient temperature, in dry conditions away from direct sources of light, in accordance with the manufacturer's recommendations. The shelf life is based on an assessment of the seal integrity of the sterile barrier packaging after accelerated aging, performance testing of device after accelerated aging and Sterility test after accelerated aging.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison between proposed device and predicate device

Item	**Proposed device**	**Predicate Device** K072739
Product	Disposable insulin syringe	Sterile Insulin Syringe for single use with fixed needle
Product Code	FMF	FMF
Regulation Number	21 CFR 880.5860	21 CFR 880.5860
Intended Use	The disposable insulin syringe is intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	The Sterile Insulin Syringe for single use with fixed needle is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin
Feature	Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap	Orange Needle cap, Fixed Needle; Piston; Plunger; Barrel; Orange Protective end cap
Sterile	Yes	Yes
Single Use	Yes	Yes
Color Coding	Yes	Yes
Performance	ISO 9626:1991, AMENDMENT 1 2001 ISO 8537:2007	Unknown
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards

10. 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.