JUL 2 5 2014

Exhibit #3 510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K141359

1. Date the summary was prepared: April 5, 2014

2. Sponsor Identification

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

Establishment Registration Number: 3005670221

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Position: General Manager
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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Name: Hard pack syringe
Proposed Device Common Name: Syringe with or without needle

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

Indications for Use:

Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body.

Needles are intended to be used with a legally marketed syringe intended to inject fluids into or withdraw fluids from the body.

5. Predicate Device Identification

510(k) Number: K113091
Product Name: Syringes with or without needles; Needles
Manufacturer: Jiangyin Caina Technology Co., Ltd.

6. Device Description

The proposed devices contain syringes and needles with various models. All the models for syringes and needles follow same design principle respectively; the differences are the size of the devices. The proposed devices are intended to inject fluids into or withdraw fluids from the body.

The proposed devices would be available in two different configurations: Syringe with needle and Syringe without needle.

Proposed devices are provided radiation (Co60) sterilized with a hard pack package which could maintain the sterility of the devices for five years. They are for single use only.

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 7886-1:1993 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use;
- ISO 7864:1993 Sterile hypodermic needles for single use.
- ISO 9626:1991, AMD 1 2001 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.
- ISO11137-2:2012, Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Devices	Predicate Devices K113091
Product Code	FMF& FMI;	FMF& FMI;
Regulation Number	21CFR 880.5860 & 21 CFR 880.5570	21CFR 880.5860 & 21 CFR 880.5570
Intended Use	Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body. Needles are intended to be used with a legally marketed syringe intended to inject fluids into or withdraw fluids from the body.	Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body. Needles are intended to be used with a legally marketed syringe intended to inject fluids into or withdraw fluids from the body.
Component	Syringes and Needles	Same
Sterile	Yes	Same
Single Use	Yes	Same
Shelf Life	Five year	Same
Biocompatibility	ISO 10993:5 Standard ISO 10993:10 Standard	Same

Performance	ISO 7864 Standard ISO 7886 Standard ISO 9626 Standard ISO 594-1 Standard SIO 594-2 Standard	Same
Immediate Package	Hard pack package	Soft package

The proposed devices, Hard pack syringe, are determined to be Substantially Equivalent (SE) to the predicate devices, Syringes and needles (K113091), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2014

Jiangyin Caina Technology Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
Post Office Box 120-119
Shanghai
CHINA 200120

Re: K141359
Trade/Device Name: Hard pack syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: June 23, 2014
Received: June 30, 2014

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

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

Exhibit #2 Indications for Use

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)*
K141359

Device Name
Hard pack syringe

Indications for Use *(Describe)*

Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body.

Needles are intended to be used with a legally marketed syringe intended to inject fluids into or withdraw fluids from the body.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman -S
Date: 2014.07.25
08:45:03 -04'00'

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