OCT 2 8 2011

Section III 510(k) Summary

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

The assigned 510(k) Number: K113091

1. Date of Submission: 27 AUG 2011.

2. Sponsor
   Jiangyin Caina Technology Co., Ltd.
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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: Syringes with or without needles
   Classification: Class II
   Product Code: FMF
   Regulation Number: 21 CFR 880.5860
   Review Panel: General Hospital
   Intended Use Statement:
   Syringes with or without needle are intended to inject fluids into or withdraw fluids from the body.

Proposed Device Name: Needles
Classification: Class II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital
Intended Use Statement:
Needles are intended to be used with a legally marketed syringe intend to inject fluids into or withdraw fluids from the body.

5. Predicate Device Identification

510(k) Number: K072739
Product Name: Sterile Hypodermic Syringe for single use, with/without needle and Sterile Hypodermic Needle for single use
Manufacturer: Shandong Weigao Group Medical Polymer Products Co., Ltd

6. Device Description

The proposed devices include: a standard piston syringes consisting of the proposed syringes consist of three components: (1) barrel, (2) piston and (3) plunger rod, and a needle consists of (1) needle tube, (2) needle hub and (3) needle sheath. They would be available in three different configurations respectively as follows:

Configuration 1 Syringes with Needle
Proposed syringes will be provided along with a proposed needle in one single package. The combinations of sizes are various upon the request of the users.

Configuration 2 Syringes without Needle
Proposed syringes will be provided without a needle. The combination of sizes are various upon the request of the users. a) It could be used together with any other U.S. legally marketed hypodermic needle with luer slip female connector complied with ISO594-1:1988 or luer lock female connector complied with ISO 594-2:1996.

Configuration 3 Needles
Proposed needles will be provided alone, which could be used together with any other U.S. legally marketed syringes with luer slip male connector complied with ISO594-1:1988 or luer lock male connector complied with ISO 594-2:1996 to complete its intended use.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device per 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, AMENDMENT 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.

8. Substantially Equivalent Conclusion

Compared with the predicate devices, the proposed devices are mainly different in size specifications and sterilization method from the predicate devices. But the sterilization validation was performed to demonstrate that the SAL of the proposed device were the same to that of the predicate devices, and the performance of both proposed and predicate device complied with same performance standards.

The proposed devices, are determined to be Substantially Equivalent (SE) to the predicate devices, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 28 2011

Jiangyin Caina Technology Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K113091
Trade/Device Name: Syringes, With or without Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: September 28, 2011
Received: October 19, 2011

Dear Mr. Mouser:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K113091
Device Name: Syringes, with or without needles

Indications for Use:

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

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

10/28/11

ivision Sign-Off)
ision of Anesthesiology, General Hospital
iection Control, Dental Devices

510(k) Number: K113091

Indication for Use

510(k) Number: K113091
Device Name: Needles

Indications for Use:

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

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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