DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 14, 2015

Jiangyin Caina Technology Co., Ltd
c/o Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K152323
Trade/Device Name: Disposable Infusion Needle, Safelock Disposable Infusion Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration set
Regulatory Class: II
Product Code: FPA
Dated: November 10, 2015
Received: November 13, 2015

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 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)*
K152323

Device Name
Safelock Disposable Infusion Needle
Disposable Infusion Needle

Indications for Use *(Describe)*
Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient' s vascular system through the needle inserted into the vein.

Safelock Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needlesticks.

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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510(k) Summary K152323

510(k) Submitter

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Device Name

Trade Name: Disposable Infusion Needle
Safelock Disposable Infusion Needle
Common Name: Intravenous Infusion Needle

Classification Name: Set, Administration, Intravascular
Classification: II;
Product Code: FPA
Regulation Number: 21CFR 880.5440
Review Panel: General Hospital

Predicate Device

Predicate Device
510(k) Number: K070362
Product Name: SURFLO Winged Infusion Set

Reference Device
510(k) Number: K132153
Product Name: SafeTouch PSV winged Infusion Set with/without filter

Device Description

The proposed devices are intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein. The device contains a conical fitting provides a standard female luer lock connector which may connect to an I.V. administration set with a male conical fitting. And the infusion needle is inserted patient's vein. Then the solution will be administered from the I.V. administration set through the infusion needle into patient vascular by gravity.

Intended Use

Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein.

Safelock Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needle sticks.

Technological Characteristics

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K070362	Reference Device K132153
Product	Disposable Infusion Needle Safelock Disposable Infusion Needle	SURFLO Ⓡ Winged Infusion Set	SafeTouch PSV winged Infusion Set with/without filter
Product Code	FPA	FPA	FOZ
Regulation Number	880.5440	880.5440	880.5200
Indications for Use	Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient' s vascular system through the needle inserted into the vein. Safelock Disposable Infusion Needle is intended to administer fluid by using an infusion set to a patient's	The Surflo Winged Infusion Set is intended to access the peripheral vascular system, for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices	The Safe Touch PSV Winged Infusion Set with/without filter is intended to be used for insertion into a patient's vascular system for single use as an indwelling device to administer fluids intravenously.

	vascular system through the needle inserted into the vein, and the safety sheath is designed to prevent accidental needle sticks.		Secondly it is designed with an active sharp feature that requires physical action by the clinician to prevent accidental needle sticks.
Intended Use	To administer fluid into the vein	To administer fluid into the vein and withdraw blood specimens	To administer fluids into the vein
Safety Feature	The Safelock Disposable Infusion needle is locked in safety sheath by withdraw safety needle handle backward	None	The Safe Touch PSV Winged infusion set needle is locked in safety sheath by withdraw safety needle handle backward
Sterile	EO sterilized	EO sterilized	EO sterilized
Blood sampling	None	Yes	None
Single Use	Single use	Single use	Single Use
Performance	Complied with ISO 9626:1991, AMENDMENT 1 2001 and ISO 7864:1993	Complied with ISO 9626:1991, AMENDMENT 1 2001 and ISO 7864:1993	
Biocompatibility	Conform with ISO 10993	Conform with ISO 10993	Conforms with ISO 10993

The subject devices are equivalent to the predicate devices with respect to technological characteristics. They shared the same operational principle, intended use, materials, biocompatibility, and sterilization.

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 7864: 1993 Sterile hypodermic needles for single use
- 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 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.
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2006 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ASTM F 756-13 Standard practice for assessment of hemolytic properties of materials. The test provided in this submission include:

Simulated Clinical Study performed on the proposed device:

A simulated clinical study was performed according to FDA *Guidance for Industry and FDA Staff*: *Medical Devices with Sharps Injury Prevention Feature*, issued on August 9, 2005 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Conclusion

Based on the non-clinical tests above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.