K103587

APR - 6 2011

Section III. 510(k) Summary

Disposable Blood Collection Needle

Weihai Hongyu Medical Devices Co., Ltd.

(As required by 21 CFR 807.92)

1. Date Prepared: Nov.18, 2010

2. Sponsor Information

Weihai Hongyu Medical Devices Co., Ltd.
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3. Submission Correspondent

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4. Proposed Device Information

Device Common or Usual name: Disposable Blood Collection Needle;
Device Trade or Proprietary Name: Blood Collection Needle
Classification Name: Needle, Hypodermic, Single Lumen;
Regulatory Class: II
Regulation number: 21CFR 880.5570;
Product Code: FMI;
Panel: General Hospital
Model: 18G, 20G, 21G, 22G, 23G

5. Predicate Device

Blood Collection Needle (K073127)

6. Device Description

Blood collection needle is a sterile and disposable medical device. It is consist of a puncturing needle which is punctured into vein, a bottle needle which is insert to the blood collection bottle to collect blood, a needle holder which connects the puncturing needle and bottle needle, two needle caps which protect puncturing needle and bottle needle and a latex cover to protect bottle needle.

7. Intended use

Disposable Blood Collection Needles is designed for use in the daily blood collection routine when delegated by a qualified practitioner.

8. Substantial Equivalence

The Disposable Blood Collection Needles shares the similar indications for use, design features, functional features, same safety compliance. Therefore the proposed device is **substantially equivalent (SE)** to the predicate devices.

9. Testing

The Disposable Blood Collection Needle is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

ISO 7864:1993 Sterile hypodermic needles for single use;
ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices/ Amendment:2001
ISO 10993, Biological Evaluation of Medical Devices; Including:
ISO 10993-1:2003, Biological Evaluation of Medical Devices – Part 1: Guidance on selection of tests;
ISO 10993-4:2002, Biological Evaluation of Medical Devices – Part 4: Selection of test for interactions with Blood
ISO 10993-5:1999, Biological Evaluation of Medical Devices – Part 5: Test for in vitro cytotoxicity;
ISO 10993-10:2002, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity;
ISO 10993-11:2006, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity;
ISO 10993-12:2002, Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials

Non-Clinical Conclusion:
Laboratory testing was conducted to validate and verify that the proposed device, Disposable Blood Collection Needle met all design specifications and was substantially equivalent to the predicate device. No Clinical Information is required

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

Weihai Hongyu Medical Devices Company, Limited
C/O Ms. Diana Hong
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Shanghai
CHINA 264200

APR - 6 2011

Re: K103587
Trade/Device Name: Disposable Blood Collection Needle 18G, 20G, 21G, 22G, 23G
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 18, 2011
Received: March 21, 2011

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 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,

for Z

Anthony 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 Statement

510(k) Number: _____

Device Name: **Disposable Blood Collection Needle**
18G, 20G, 21G, 22G, 23G

Indications for Use:

Disposable Blood Collection Needles is designed for use in the daily blood collection routine when delegated by a qualified practitioner.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/6/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control and Dental Devices
510(k) Number: K103587

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