K083429

AUG 07 2009

Chapter III 510(k) Summary

I.V. Catheter for Single Use

As required by 21 CFR 807.92(k)

The assigned 510(k) Number is: _____

1. Date Prepared: November 15, 2008;

2. Sponsor Information

Weihai Jierui Medical Products Co., Ltd.
No.348, Shichang Road, Weihai, Shandong, 264209, China

Contact Person: Mrs. Zhao Suxia, Quality Manager
Tel: +86-631-5621632
Fax: +86-631-5620555
E-Mail: Zsx9001@sina.com

3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China

4. Device Name and Classification:

Device Trade Name: I.V. Catheter for Single Use
Type: Type I, Type Y and Type Straight
Device Classification Name: Intravascular Catheter
Product Code: FOZ
Regulation Number: 880.5200
Device Class: II

K083429 Pg 1 of 2

5. Predicate Device Identification:
   K991406
   Trade/Proprietary Name: TERUMO Surflo Flex I.V. Catheter
   Submitter Name: Terumo Medical Corporation

6. Intended Use:

   I.V. Catheter for Single Use, including Type I, Type Y and Type Straight, is intended to be inserted into a patient's vascular system for short term use to sample blood, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors.

7. Device Description:

   The proposed device, I.V. Catheter for Single Use including Type I, Type Y and Type Straight, is intended to be inserted into a patient's vascular system for short term use to sample blood, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors. It is provided EO sterilized, latex free, prygon-free and DEHP-free. All types are available in four sized, which are 18G, 20G, 22G and 24G.

   Type Straight Catheter for Single Use consists of a sheath, slender catheter tubing, stainless steel needle, catheter hub, needle wing, catheter body, clamp and straight connector. Type Y I.V. Catheter for Single Use consists of a sheath, slender catheter tubing, stainless steel needle, catheter hub, needle wing, catheter body, clamp and Y connector. And Type I I.V. Catheter for single Use consists of a sheath, slender catheter tubing, stainless steel needle, catheter hub, needle handle and vent fitting. Type Straight and Type Y are closed system while Type I is open system.

8. Test Conclusion

   Laboratory testing was conducted to validate and verify that I.V. Catheter for Single Use met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:
   The proposed device, Blood Transfusion Set, is substantially equivalent to the predicate device.

K083429 Pg 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 07 2009

Weihai Jierui Medical Products Company, Limited
C/O Ms. Diana Hong
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, Zhongshan Zhongxin Mansion
No. 19, Lane 999, Zhongshan No. 2 Road(S)
Shanghai, 200030
CHINA

Re: K083429
Trade/Device Name: I.V. Catheter for Single Use
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 17, 2009
Received: July 22, 2009

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.

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

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

Enclosure

Indication for Use

510(k) Number: K083429

Device Name: I.V. Catheter for Single Use

Indications for Use:

I.V. Catheter for Single Use, including Type I, Type Y and Type Straight, is intended to be inserted into a patient's vascular system for short term use to sample blood, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083429