K060211

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FEB 1 0 2006

510(k) Summary

Submitter Information:

Name and Address:
Wenzhou Wuzhou Group Co., Ltd.
Rm. 606-608, Dongfang Bldg., Wenzhou, China

Contact Person:
George Su
Crosslinks International
1800 Century Park East, Suite 600
Los Angeles, CA 90067
USA

Tel: 310-229-5748
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Email: crosslinks2000@aol.com

Device Name:
Trade Name: Wuzhou Syringe, with/without needle
Common Name: Sterile Piston Syringe, Hypodermic Single Lumen Needle
Classification Name: Piston Syringe, Hypodermic Single Lumen Needle

FDA Classification (class Ⅰ, Ⅱ or Ⅲ)
Piston Syringe 21 C.F.R. 880.5680, Product Code FMF, Class Ⅱ
Hypodermic Single Lumen Needle 21 C.F.R. 880.5570, Product Code FMI, Class Ⅱ

Predicate Device:
The DuoProSS Syringe (K042500) manufactured by DuoProSS Meditech Corporation.

Intended Use:
The Wuzhou Syringe, with/without needle is intended to be used for medical purposes to inject fluids

into or withdraw fluids from the body. K46421 (P.2 of 4)

Principle of Operation and Technology:
The Wuzhou Syringe, with/without needle is designed for manual use.

Design and Materials:

The Wuzhou Syringe, with/without needle, consists mainly of 3 parts or 4 pars: a barrel, a plunger, a gasket and a needle (for the needle type). The barrel and the plunger are made from medical polypropylene. The gasket is made from rubber (not include emulsion and natural rubber). The needle is made from stainless steel. The lubricant on barrel is the Polydimethylsiloxane oil.

Description of Device:

The Wuzhou Syringe, with/without needle, is a standard piston syringe that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The syringe is designed for manual use. It is available in 1, 2, 3, 5, 10, 20, 30, 50, 60 and 100ml volumes, with luer slip, luer lock, centrally or eccentrically tip configurations. Syringe with 50 ml volume is irrigating syringe.

Declaration of the Conformance to Applicable Standards

The Wuzhou Syringe, with/without needle, complies with:

-- GB 15810-2001, which is equal to specific sections of ISO 7886-1 Guidance for Sterile Hypodermic Syringe for Single Use, Part 1: Syringe for manual use.

-- GB 15811-2001, which is equal to ISO 7864, Sterile Hypodermic needles for Single Use;

-- GB/T 1962.1-2001, equals to ISO 594-1:1986, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment, Part 1: General Requirements;

-- GB/T 1962.2-2001, equals to ISO 594-2:1998, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment, Part 2: Lock Fitting;

-- GB18279-2000, equals to ISO 11135, Medical Devices-Validation and Routine Control for Ethylene Oxide Sterilization;

-- GB18457-2001, equals to ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices;

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-- JGJ71-1990, Practice of constructing and verifying clean room

-- GB/T 16292-1996, equals to FS/209E (withdrawn from use in USA), Test method for airborne particles in clean room (area) of the pharmaceutical industry. And FS/209E is still in use in the pharmaceutical industry in USA, Japan, some European Countries and China.

-- ISO 10993, Biological Evaluation of Medical Devices;
ISO 10993-1: Evaluation and Testing,
ISO 10993-5 Tests for Cytotoxicity
ISO 10993-10 Tests for irritation and Sensitization,
ISO 10993-4 Tests for interactions with blood,
ISO 10993-11 Test for systemic toxicity.

-- FDA guidance document," Guidance on the Content of Premarket Notification [510(k)] Submission for Piston Syringes", dated April 1993.

Substantial Equivalence Comparison:

The Wuzhou Syringe, with/without needle, is substantially equivalent to the predicate DuoProSS Syringe as follows:
1. Intended Uses: Both The Wuzhou Syringe, with/without needle, and DouProSS Syringe are intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

2. Labeling: Both of their labeling include the identity of the device (type, size, needle gauge and length), quantity and the required warnings and prescription statement according to 880.5860(b) (1).

3. Design and materials: The design of Wuzhou Syringe and DuoProSS Syringe are basically the same. Both devices are comprised of a barrel, plunger, gasket and needle. The materials of them are totally the same.

4. Specifications: The physical specifications of Wuzhou Syringe, with/without needle, and DuoProSS Syringe are basically the same. The difference between them is syringe sizes and needle length. Both of the Mechanical and Biological conform to the same international standard.

Substantial Equivalence Summary:
In summary, The Wuzhou Syringe, with/without needle, is substantially equivalent in intended use, labeling, design and materials, and specifications to the predicate DuoProSS Syringe (K042500) manufactured by DuoProSS Meditech Corporation. Any noted differences between the two devices do

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not raise new issues of the safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2006

Wenzhou Wuzhou Group Company, Limited
C/O Ms. Laura Danielson
Responsible Third Party Official
TÜV America, Incorporated
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K060211
Trade/Device Name: Wuzhou Syringe with/Without Needle
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 26, 2006
Received: January 27, 2006

Dear Ms. Danielson:

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.

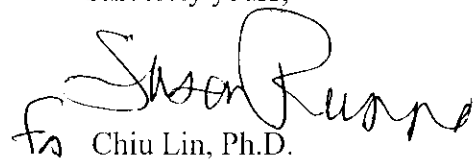
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K964211

Device Name: Wuzhou Syringe With/Without Needle

Indications for Use:

The Wuzhou Syringe, with/without needle for single use only, is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible], General Hospital, [illegible]

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