

**510(k) SUMMARY**

AUG 11 2006

**1. Submitter's Identification:**

Wuxi Yushou Medical Appliances Co., Ltd.  
215#XiGang Road, DongbeiTang  
WuXi City – JiangSu – 214191 - China  
Telephone (262) 636-8957  
Facsimile (262) 636-9760  
Contact Timothy Llewellyn

Date Prepared: September 19, 2005 – Updated August 9, 2006

**2. Device Name:**

Trade/ Proprietary Name	Safety Syringe
Common Name	Syringe
Classification Name	Syringe, Antistick
Class	Class II, per 21 CFR § 880.5860
Product Code	MEG

**3. Predicate Device(s):**

BD Spring Based Syringe (K011103)

**4. Description and Intended Use:**

The Safety Syringe per (21 CFR § 880.5860) is a device intended for medical purposes 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. Size variations are listed below.

The device's primary intended use is general purpose injection of fluids into, or withdrawal of fluids from the body, below the surface of the skin except for phlebotomy. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

**510(k) SUMMARY (cont'd.)**

Following are the size variations.

**Syringes Sizes**

1cc

3cc

5cc

10cc

**Pre-Tipped Syringes**

1cc - 27g x 3/8"

1cc - 27g x 1/2"

1cc - 26 g x 3/8"

1cc - 25 g x 5/8"

1cc - 22 g x 1 1/2"

3cc - 25 g x 5/8"

3cc - 25 g x 1"

3cc - 23 g x 1"

3cc - 22 g x 3/4"

3cc - 22 g x 1"

3cc - 22 g x 1 1/2"

3cc - 21 g x 1"

3cc - 21 g x 1 1/2"

3cc - 20 g x 1"

3cc - 20 g x 1 1/2"

10cc - 21 g x 1"

10cc - 20 g x 1"

**Needles Sizes**

27g x 1/2"

25g x 5/8"

25g x 1"

25g x 1 1/2"

23g x 1"

22g x 1"

22g x 1 1/2"

20g x 1 "

20g x 1 1/2"

18g x 1"

18g x 1 1/2"



AUG 11 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Wuxi Yushou Medical Appliances Company, Limited  
C/O Mr. Gary Pond  
CEO  
Inter-Med, Incorporated  
2200 Northwestern Avenue  
Racine, Wisconsin 53404

Re: K053519  
Trade/Device Name: Safety Syringes 1 cc, 3 cc, 5 cc, and 10 cc  
Regulation Number: 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: MEG  
Dated: July 17, 2006  
Received: July 20, 2006

Dear Mr. Pond:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are 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 devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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): K053519

Device Name: Safety Syringe

Indications for Use:

The device's primary intended use is general purpose injection of fluids into, or withdrawal of fluids from the body, below the surface of the skin except for phlebotomy. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

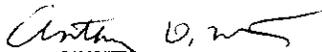
Prescription Use  X   
(Part 21 CFR 801 Subpart D)

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)  
Department of Anesthesiology, General Hospital,  
Regulatory Control, Dental Devices

Device Number: K053519