K132553

Section_005 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: 12. 08.2013

1. Submitter Name and Address:

Owner Name: U&U Medical Technology Co., Ltd
Address: Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
RM C1-D 6/F WING HING IND BLDG 14 HING YIP ST KWUN TONG KLN HONG KONG
Contactor Name: Xuebo Wang
TEL: +86-13564751751
E-mail: Blackwang@tkmedical.com

Contract Manufacturer Name: ANHUI TIANKANG MEDICAL PRODUCTS CO., LTD.
Address: No 20 south renhe road tianchang, CHINA 239300
Web: www.tkmedical.com

US Agent:
US Agent: Pan Angels Corp.
Address: 3330 Fowler Street, Los Angeles, CA 90063,U.S.A
TEL: (323)422-8581
Contact person : Mr. Michael Kim

2. Submission Devices Information:

Trade/Proprietary Name: U&U Sterile Piston Syringe without needle
Common Name: Piston Syringe
Classification name:Piston Syringe.
Class: II.
Panel: 80.
Procodes: FMF - Piston Syringe

3. Predicate Devices Information:

1. Piston Syringe:
   Trade Name: BD Single Use, Hypodermic Syringe
   510(K) Number: K110771

4. Devices Description:

Sterile Piston Syringes

The piston syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male Luer Slip/Lock connector (nozzle) for attaching the female Luer connector (hub) of a hypodermic single lumen needle, or for attaching other devices with a female Luer. The syringe is sterilized by EtO gas. And it is a Non-Pyrogenic and single use device. The mainly raw materials are PP, PE and rubber.

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Ref Number	Model Number	Description	Size
TKSLS001	TKSLS	Piston syringe (LUER SLIP)	1cc/ml
TKSLS002	TKSLS	Piston syringe (LUER SLIP)	2cc/ml
TKSLS003	TKSLS	Piston syringe (LUER SLIP)	3cc/ml
TKSLS004	TKSLS	Piston syringe (LUER SLIP)	5cc/ml
TKSLS005	TKSLS	Piston syringe (LUER SLIP)	10cc/ml
TKSLS006	TKSLS	Piston syringe (LUER SLIP)	20cc/ml
TKSLS007	TKSLS	Piston syringe (LUER SLIP)	30cc/ml
TKSLS008	TKSLS	Piston syringe (LUER SLIP)	50cc/ml
TKSLS009	TKSLS	Piston syringe (LUER SLIP)	60cc/ml

TKSLL001	TKSLL	Piston syringe (LUER LOCK)	1cc/ml
TKSLL002	TKSLL	Piston syringe (LUER LOCK)	2cc/ml
TKSLL003	TKSLL	Piston syringe (LUER LOCK)	3cc/ml
TKSLL004	TKSLL	Piston syringe (LUER LOCK)	5cc/ml
TKSLL005	TKSLL	Piston syringe (LUER LOCK)	10cc/ml
TKSLL006	TKSLL	Piston syringe (LUER LOCK)	20cc/ml
TKSLL007	TKSLL	Piston syringe (LUER LOCK)	30cc/ml
TKSLL008	TKSLL	Piston syringe (LUER LOCK)	50cc/ml
TKSLL009	TKSLL	Piston syringe (LUER LOCK)	60cc/ml

5. Intended Use:

Sterile Piston Syringes
U&U Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/ injection

6. Technological Characteristics:

Through comparisons between the submitted devices with the predicate devices as follows tables. We believe the applicant devices are substantially equivalent with the predicate devices.

Sterile Piston Hypodermic Syringes Comparison Table

Element of Comparison	Submission Device	Predicate Device K110771
Intended Use	U&U Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/ injection	The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/ injection.
Principle of Operation	Normal	Normal
Syringe Capacity	Various Sizes	Various Sizes
Nozzle Type	Luer Slip & Luer Lock	Luer Slip & Luer Lock
Lubricant for Barrel	Silicone Oil	Silicone Oil
Barrel Transparency	Transparent and Clear	Transparent and Clear
Gradations Legibility	Legible	Legible

Materials **Barrel** **Plunger** **Piston**	 PP PE Rubber	 PP PE Rubber
Performances	Conforms to ISO7886-1	Conforms to ISO7886-1
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent.

END

Kuobo Wang

Aug. 12. 2013

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 27, 2014

U&U Medical Technology Company, Limited
Xuebo Wang
Regulatory Affairs Manager
Dongzhou Village, Hengshanqiao Town, Changzhou
Jiangsu, China 213119

Re: K132553
Trade/Device Name: U&U Sterile Piston Syringe without Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: December 8, 2013
Received: January 29, 2014

Dear Mr.Wang:

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,

Kwame O. Ulmer S

for

Erin I. Keith, M.S.
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132553

Device Name
U&U Sterile Piston Syringes Without Needle

Indications for Use *(Describe)*
U&U Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/injection.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by
Richard C. Chapman
Date: 2014.02.25
09:02:57 -05'00'

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