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

March 25, 2016

U&U Medical Technology Co., Ltd.
Black Wang
General Manager
Dongzhou Village, Hengshanqiao
Changzhou, Jiangsu 213119
CHINA

Re: K152808
Trade/Device Name: U&U Insulin Syringe with/without Safety Retractable Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: MEG and FMF
Dated: February 18, 2016
Received: February 19, 2016

Dear Black 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tina Kiang
-S

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152808

Device Name
U&U Insulin Syringe with/without Safety Retractable Device

Indications for Use *(Describe)*
The U&U Insulin Syringe with Safety Retractable Device is a sterile, single use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

The U&U Insulin Syringe is a sterile, single use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K152808 510(K) Summary

Date Prepared: March 9, 2016

The assigned 510(k) Number: K152808

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:
Name: CARELIFE (USA) INC.
Address: 1580 Boggs Rd, Suite 500/600 Duluth GA 30096
TEL: 404-661-2228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

2. Submission Devices Information:

Trade/Proprietary Name: U&U Insulin Syringe with/without Safety Retractable Device
Common Name: Syringe, Antistick Piston Syringe
Classification name: Piston Syringe.
Class: 2
Panel: 80
Product codes: MEG and FMF
Submission Type: 510(k) Traditional
Regulation Number: 880.5860

3. Predicate Devices Information:

Trade Name: InsoSAFE BakSNAP Retractable Insulin Safety Syringe
510(K) Number: K050131
Company: M.K. Meditech Co., Ltd

Trade Name: Disposable Insulin Syringe
510(K) Number: K151949
Company: Jiangyin Caina Technology Co., Ltd.

4. Devices Description:

The U&U Insulin Syringe with/without Safety Retractable Devices are similarl devices except one has a safety feature and the other is a standard insulin syringe.
The U&U Insulin Syringe with/without Safety Retractable Device is an integrated needle and piston syringe with an anti-needle-stick mechanism. The mechanism allows clear visualization of

the injection site at all times. The mechanism shows the needle is contained within the syringe barrel. After standard techniques for injection, the plunger is withdrawn and snapped off which renders the needle unusable and prevents accidental needle sticks. The used syringe is then discarded into a sharps container.

The subject devices are sterile, single use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

The U&U Insulin Syringe with/without Safety Retractable Device will be available in numerous sizes and combinations between the smallest (0.3cc/ml + 31G) and the largest (1cc/ml + 27G)

Ref Number	**Model Number**	**Description**	**Size**
UUIS001	UUIS	Insulin Syringe	0.3cc/ml Needle 27G to 31G
UUIS002	UUIS	Insulin Syringe	0.5cc/ml Needle 27G to 31G
UUIS003	UUIS	Insulin Syringe	1cc/ml Needle 27G to 31G
UUSIS001	UUSIS	Insulin Syringe with Safety Retractable Device	1cc/ml Needle 27G to 31G

5. Intended Use:

The U&U Insulin Syringe with Safety Retractable Device a sterile, single use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

The U&U insulin syringe is a sterile, single use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

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.

Comparison Table

Element of Comparison	Submission Device	Predicate Device K050131	Predicate Device K151949
Intended Use	The U&U Insulin Syringe with Safety Retractable Device a sterile, single use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse. The U&U insulin syringe is a sterile, single use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.	The InsoSAFE BakSNAP Retractable Insulin Safety Syringe a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	The disposable insulin syringe is intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.
Principle of Operation	Normal	Normal	Normal

Syringe Capacity	0.3cc/ml Needle 27G to 31G 0.5cc/ml Needle 27G to 31G 1cc/ml Needle 27G to 31G U&U Insulin Syringe with Safety Retractable Device: 1cc/ml only needle 27G to 31G	Various Sizes	0.3ml 0.5ml 1ml
Nozzle Type	N.A	N.A	N.A
Lubricant for Barrel	Silicone Oil	Silicone Oil	Polydimethylsiloxane
Barrel Transparency	Transparent and Clear	Transparent and Clear	Transparent and Clear
Gradations Legibility	Legible	Legible	Legible
Materials **Barrel** **Plunger** **Piston** **Needle Hub** **Needle** **Needle Sheath**	 PP PP TPE PP Stainless Steel PP	 PP PP Silicone PP Stainless Steel PP	 PP PP Polysoprene PP Stainless Steel PE
Needle Gauge and Length	Various Sizes	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil	Polydimethylsiloxane
U&U Insulin Syringe with Safety Retractable Device: Sharps Injury Prevention Features	Manual Retractable Conforms to ISO 23908	Manual Retractable Conforms to ISO 23908	N.A
Performances	Conforms to ISO7864 ISO8537	Conforms to ISO7864 ISO8537	Conforms to ISO7864 ISO8537
Biocompatibility	Conforms to ISO10993 (Part 1: Evaluation and testing, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation anddelayed-type hypersensitivity, Part 11: Tests for systemic toxicity)	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Non-Clinical Tests performed on the subject device.

The proposed devices were tested per the following standards, to evaluate its performance.

- ISO 8537 Second edition 2007-10-01 Sterile single-use syringes, with or without needle, for insulin.
- ISO7886-1:1993 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO7864:1993 Sterile hypodermic needles for single use

For the U&U Insulin Syringe with Safety Retractable Device Only:
- ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices.

ISO 23908 Sharps Injury Prevention

Guidance document.
Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071663.htm

The test items include following.

- Insulin Syringe Physical Performance - Needle length
- Insulin Syringe Physical Performance - Diameter
- Insulin Syringe Physical Performance - Gauge
- Insulin Syringe Physical Performance - Hub/needle bond strength
- Insulin Syringe Physical Performance - Cover strength
- Insulin Syringe Physical Performance - Patency of Needle lumen
- Insulin Syringe Physical Performance - Resistance to breakage
- Insulin Syringe Physical Performance - Stiffness
- Insulin Syringe Physical Performance - Resistance to corrosion
- Insulin Syringe Physical Performance - Maximum Dead Space
- Insulin Syringe Physical Performance - Freedom from leakage at needle
- Insulin Syringe Physical Performance - Freedom Liquid and air leakage past piston
- Insulin Syringe Physical Performance - Force required to Operate plunger
- Sharps Injury Prevention Features - Force to activate safety feature
- Insulin Syringe Physical Performance - Tolerance on graduated capacity (Dose accuracy)

Biocompatibility

Conforms to ISO10993
Part 1: Evaluation and testing,
Part 4: Selection of tests for interactions with blood,
Part 5: Tests for in vitro cytotoxicity,
Part 7: Ethylene oxide sterilization residuals,
Part 10: Tests for irritation and delayed- type hypersensitivity,
Part 11: Tests for systemic toxicity

8. Conclusion:

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