K132552

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:

NOV 1 3 2013

Trade/Proprietary Name: U&U Sterile Hypodermic Needle
Common Name: Hypodermic Needle
Classification name: Hypodermic Needle.
Class: 2.
Panel: 80.
Product codes: FMI - Hypodermic Single Lumen Needle
Submission Type: 510(k)
Regulation Number: 880 5570

3. Predicate Devices Information:

Hypodermic Needle:
Trade Name: BD Hypoint™ Hypodermic Needle.
510(K) Number: K070440

4. Devices Description:

U&U Sterile Hypodermic Needle

The U&U Sterile Hypodermic Needle is a hypodermic single lumen needle, designed for use with syringes and injection devices for general purpose fluid injection / aspiration. The U&U Sterile Hypodermic Needle are offered in various gauge sizes and needle lengths. The U&U Sterile

Hypodermic Needle is sterilized by EtO gas. The U&U Sterile Hypodermic Needle is Non-Pyrogenic, disposable and intended for single use.

Ref Number	Model Number	Description	Length	Gauge
TKHN_001	TKHN	Hypodermic Needle Normal-walled	1/2 to 1"	30G
TKHN_002	TKHN	Hypodermic Needle Normal-walled	1/2 to 1"	29G
TKHN_003	TKHN	Hypodermic Needle Normal-walled	1/2 to 1"	28G
TKHN_004	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	27G
TKHN_005	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	26G
TKHN_006	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	25G
TKHN_007	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	24G
TKHN_008	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	23G
TKHN_009	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	22G
TKHN_010	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	21G
TKHN_011	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	20G
TKHN_012	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	19G
TKHN_013	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	18G
TKHN_014	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	17G
TKHN_015	TKHN	Hypodermic Needle Normal-walled	1 to 1 1/2"	16G

5. Intended Use:

U&U Sterile Hypodermic Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

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.

Element of Comparison	Submission Device	Predicate Device K110771
Intended Use	U&U Sterile Hypodermic Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	The BD Hypoint™ Hypodermic Needle is intended for use with Syringes and injection devices for general purpose fluid aspiration/ injection.
Principle of Operation	Normal	Normal
Needle Gauge and Length	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil
Adhesive	UV Glue	Epoxy Resin
Needle Hub Colors	Various Colors	Various Colors
Tip configuration	Bevel	Bevel
Materials **Needle Hub** **Needle** **Needle Cover**	 PP Stainless Steel PP	 PP Stainless Steel PE
Performances	Conforms to ISO7864	Conforms to ISO7864
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993
Labeling	Meet the requirements of 21 CFR	Meet the requirements of 21

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	Part 801	CFR Part 801

7. Conclusion:

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

END

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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

November 13, 2013

U&U Medical Technology Company, Limited
Mr. Xuebo Wang
Dongzhou Village, Hengshanqiao, Changzhou, Jiangsu, China
RM C1-D 6/F Wing Hing Industrial 14
Hing Yip Street Kwun Tong Kln
HONG KONG

Re: K132552
Trade/Device Name: U&U Sterile Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 12, 2013
Received: August 13, 2013

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division 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)*
K132552

Device Name
U&U Sterile Hypodermic Needles

Indications for Use *(Describe)*

U&U Sterile Hypodermic Needles is intended for use with syringes and injection devices for general purpose fluid injection/ aspiration.

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

Richard C. Chapman
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