SHIFENG MEDICAL GROUP

Project of Luer-Lock Syringe and Safety Needle

SHIFENG Medical Production Workshops Brief Introduction

About Us

INJECTION: High-Accuracy, High-Efficiency Injection machines.

EXTRUSION: Two-color Extrusion machines. High-Speed Extrusion machines. Dual Cavity Extrusion and High Pressure tube Extrusion.

INSPECTION TEST: More than 10 years **CNAS** Lab.

About Us

Development: Raw material patents, product patents. Mold design and Machinery R&D.

Raw material: Plastic Manufacturing.

Employees: More than 1000 and the turnover rate less than 2%.

Our Team: Professional and **Fast** response.

Cost: Good cost control and meet Customer Cost requirements.

PUXING Plant

PUXING Plant (New)

Land area: 71,000 sqm

Clean Room: 19,414 sqm

By 2019： Two workshops will be completed for producing syringe, IV set and needle.

By 2020: all four workshops, new sterilization workshop and new plastic granulation workshop will be ready for use.

Less labor, more automation (eg. material auto-loaded, automatic assembling machines, automatic package and automatic sterilization load.)

Capacity:

2 billion needles, 1.60 billion syringes, 320 million IV sets

XINPING Plant

XINPING Plant

Land area: 69,700 sqm

Clean Room: 16,800 sqm

Employees: 926

Storage area: 11,760 sqm

Capacity:
78 injection molding machines
12 extruding machines
11 EO sterilization chambers with pre-treatment
800 million syringes and 180 million IV sets
8 million hemodialysis tubes.

Pakistan Nisa.SF Plant

Pakistan Nisa.SF Plant

In 2016, bought from BD.

Largest disposable manufacturer in Pakistan.

Clean Room: 6,000 sqm

4 syringe assembling lines, 2 IV set lines, 1 IV burette line, 300 employees;

300 million syringes, 50 million IV SETS, 9 million IV burettes, 1.8 million hemodialysis tubes.


U&U MEDICAL TECHNOLOGY CO.,LTD
SHIFENG
3-PIECE PISTON SYRINGES:
Piston disposable syringes are available with Luer-Lock, Luer slip from volume 0.5/1ml to 60 ml Which are used for injection and dispensing.
CE CERTIFICATE
FDA 510K APPROVED
CE 0123
FDA

PRODUCT FEATURES :

01 3-piece Syringes are used for injecting medications using standard and specialized techniques

02 The transparent barrel ensures the controlled administration of the medication

03 Smooth-glide plunger ensures painless injection without jerking

04 Latex-free plunger seal reduces the risk of allergic reactions

05 Clearly legible graduation for safe, reliable dosage

06 Secure plunger stop prevents loss of medication

07 Broad range of needle fittings (Luer Slip, Luer Lock) provides a range of choices, depending on the indication

PACKING INFORMATION:

Blister pack for each syringe

Catalog No.	Volume ml/cc	Type	Taper	W/Without Needle	Quantity box/carton
UUPS1/2	0.5	Concentric	Luer Slip & Lock	Without	100/800
UUPS1	1	Concentric	Luer Slip & Lock	Without	100/800
UUPS3	3	Concentric	Luer Slip & Lock	Without	100/1200
UUPS5	5	Concentric	Luer Slip & Lock	Without	100/600
UUPS10	10	Concentric	Luer Slip & Lock	Without	100/600
UUPS12	12	Concentric	Luer Slip & Lock	Without	100/600
UUPS20	20	Concentric	Luer Slip & Lock	Without	50/600
UUPS30	30	Concentric	Luer Slip & Lock	Without	50/600
UUPS60	60	Concentric	Luer Slip & Lock	Without	50/600


U&U MEDICAL
TECHNOLOGY CO,LTD
SHIFENG
SAFETY SYRINGES
WITH NEEDLE:
Safety needle and safety needle combo helps to ensure safety for nurses and patients. Patented SAFETY NEEDLE is intended for use in the aspiration and is designed to ensure protection from needlestick injuries after use.
CE CERTIFICATE
FDA 510K APPROVED
CE 0123
FDA

PRODUCT FEATURES :

01 Both Safety needle and safety needle combo available for full sizes scope.

02 Mechanism design for locking.

03 High grade material and good process control ensure smooth injection and comfort for patients.

04 Color code (according to ISO Standard) for easy identification of needle size, facilitates the correct selection.

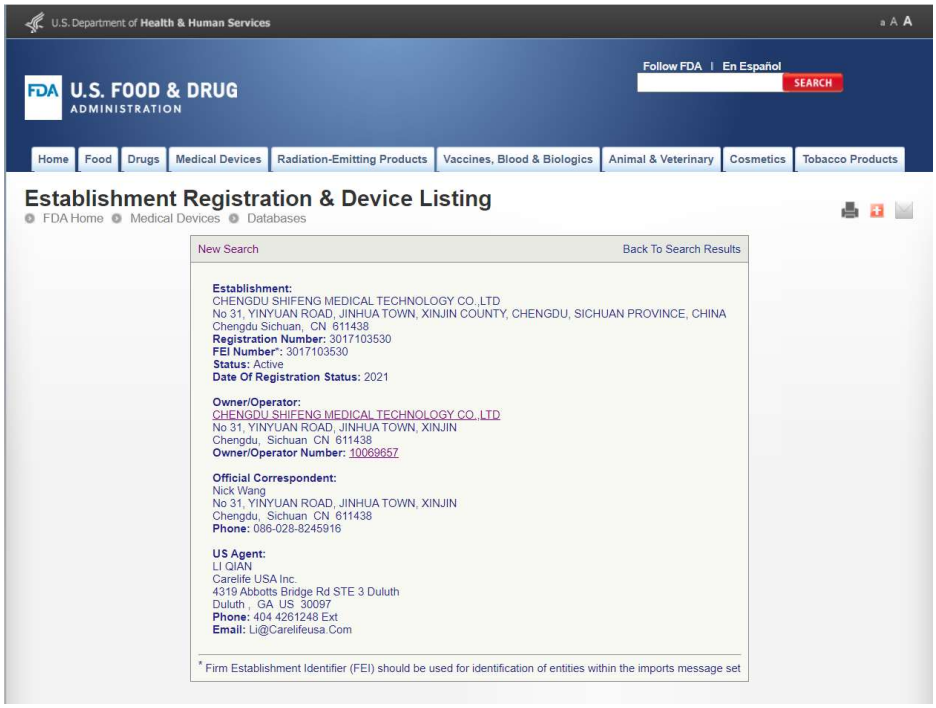
05 One-handed operation minimizes risk of needlestick injuries; easy to use with minimal technique change for the clinician.

06 Sterile. Well-biocompatible materials, NOT made by natural rubber latex.

PACKING INFORMATION:

Blister pack for each syringe

Safety Needle Spec.		
Can be preassembled with syringes of 1mL/3mL/5mL/10mL creating combo options.		
Gauge	Length	Color code
18G	3/8" to 2"	Pink
19G	3/8" to 2"	Cream
20G	3/8" to 2"	Yellow
21G	3/8" to 2"	Dark green
22G	3/8" to 2"	Black
23G	3/8" to 2"	Dark blue
24G	3/8" to 2"	Purple
25G	3/8" to 2"	Orange
27G	3/8" to 2"	Grey
30G	3/8" to 2"	Yellow



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

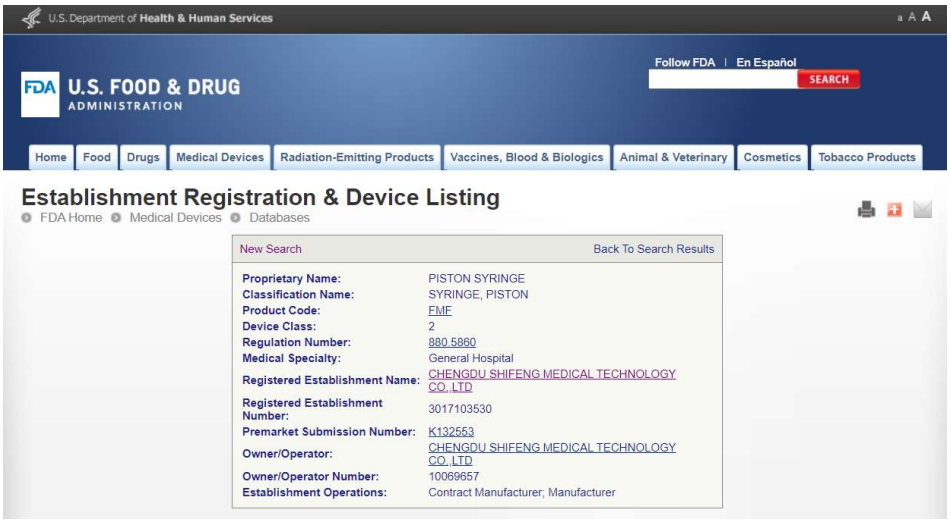
Establishment:
CHENGDU SHIFENG MEDICAL TECHNOLOGY CO.,LTD
No 31, YINYUAN ROAD, JINHUA TOWN, XINJIN COUNTY, CHENGDU, SICHUAN PROVINCE, CHINA
Chengdu Sichuan, CN 611438
Registration Number: 3017103530
FEI Number*: 3017103530
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
CHENGDU SHIFENG MEDICAL TECHNOLOGY CO.,LTD
No 31, YINYUAN ROAD, JINHUA TOWN, XINJIN
Chengdu, Sichuan CN 611438
Owner/Operator Number: 10069657

Official Correspondent:
Nick Wang
No 31, YINYUAN ROAD, JINHUA TOWN, XINJIN
Chengdu, Sichuan CN 611438
Phone: 086-028-8245916

US Agent:
LI QIAN
Carelife USA Inc.
4319 Abbotts Bridge Rd STE 3 Duluth
Duluth , GA US 30097
Phone: 404 4261248 Ext
Email: Li@Carelifeusa.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set



U.S. Department of Health & Human Services

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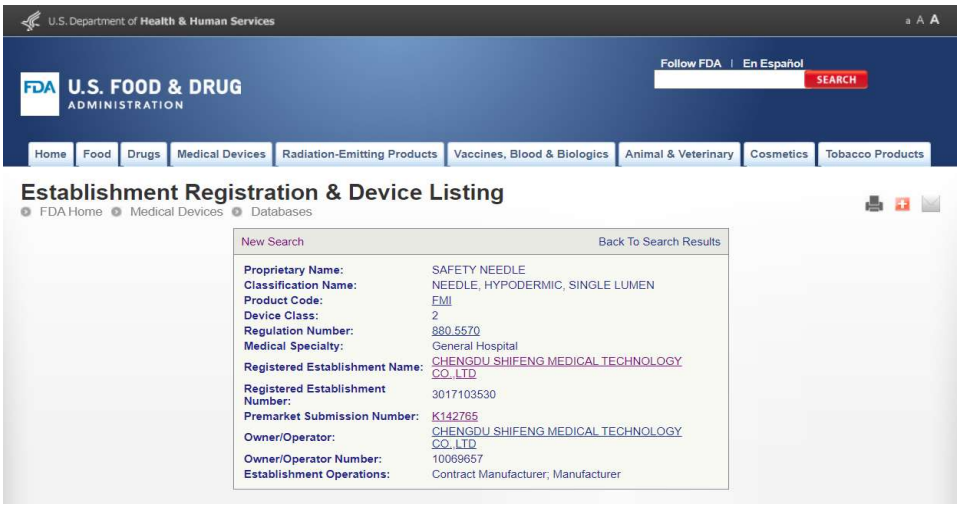
Proprietary Name:	PISTON SYRINGE
Classification Name:	SYRINGE, PISTON
Product Code:	FMF
Device Class:	2
Regulation Number:	880.5860
Medical Specialty:	General Hospital
Registered Establishment Name:	CHENGDU SHIFENG MEDICAL TECHNOLOGY CO.,LTD
Registered Establishment Number:	3017103530
Premarket Submission Number:	K132553
Owner/Operator:	CHENGDU SHIFENG MEDICAL TECHNOLOGY CO. LTD
Owner/Operator Number:	10069657
Establishment Operations:	Contract Manufacturer; Manufacturer



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Proprietary Name:	SAFETY NEEDLE
Classification Name:	NEEDLE, HYPODERMIC, SINGLE LUMEN
Product Code:	FMI
Device Class:	2
Regulation Number:	880.5570
Medical Specialty:	General Hospital
Registered Establishment Name:	CHENGDU SHIFENG MEDICAL TECHNOLOGY CO. LTD
Registered Establishment Number:	3017103530
Premarket Submission Number:	K142765
Owner/Operator:	CHENGDU SHIFENG MEDICAL TECHNOLOGY CO. LTD
Owner/Operator Number:	10069657
Establishment Operations:	Contract Manufacturer; Manufacturer

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.

000016

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

000018

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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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

August 11, 2015

ThinkMed Medical Technology Co., Ltd.
Mr. Garfield Wang
No. 4 Building, 322 Hongyang Road
Jiangsu 215341
CHINA

Re: K142765
Trade/Device Name: TM Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: September 23, 2014
Received: July 14, 2015

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 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,

Erin I. Keith -S

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

Section_004 Indications for Use

510(k) Number (if known):_____K142765__

Device Name: TM Safety Needle

Indications for Use

The TM Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TM Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) Summary

Date Prepared: 10. 08.2015

1. Submitter Name and Address:

Owner Name: ThinkMed Medical Technology Co., Ltd.
Address: No.4 Building, 322 Hongyang Road, Qiandeng Town,Kunshan City, CHINA
No 20 South Renhe Road Tianchang city, CHINA
Contactor Name: Garfield 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 6612228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

2. Submission Devices Information:

Trade/Proprietary Name: TM Safety Needle
Common Name: Safety Needle
Submission Type: Traditional 510k
Regulation Number: 21CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Product Code: FMI
Class: 2

3. Predicate Devices Information:

Trade Name: TERUMO® SurGuard®3 Safety Needle
510(K) Number: K113422
Trade Name: U&U Hypodermic Needle
510(K) Number: K132552

4. Devices Description:

TM Safety Needle

The TM Safety Needle consists of a hypodermic needle with a hinged safety sheath attached to the needle hub. The safety sheath is simultaneously activated when manually pressed over the needle after use and prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with one-hand operation by pressing the sheath either with the finger or thumb, or by surface activation.

The locking mechanism is positioned within the center and proximal end of the sheath. The hinge feature allows the medical practitioner the flexibility to adjust the sheath to its desired position for use.

NOTE: The hypodermic needle used is the U&U Hypodermic Needle, the K number is K132552.

Ref Number	Model Number	Description	Length	Gauge
TMSN001	TMSN	Safety Hypodermic Needle	1/2 to 1”	30G
TMSN002	TMSN	Safety Hypodermic Needle	1/2 to 1”	29G
TMSN003	TMSN	Safety Hypodermic Needle	1/2 to 1”	28G
TMSN004	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	27G
TMSN005	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	26G
TMSN006	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	25G
TMSN007	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	24G
TMSN008	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	23G
TMSN009	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	22G
TMSN010	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	21G
TMSN011	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	20G
TMSN012	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	19G
TMSN013	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	18G
TMSN014	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	17G
TMSN015	TMSN	Safety Hypodermic Needle	1 to 1 1/2”	16G

5. Intended Use:

The TM Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TM Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.

6. Technological Characteristics:

The following table illustrates the similarities between the TM safety needle (subject device) and the two predicate devices.

Element of Comparison	Submission Device	Predicate Device K113422	Predicate Device K132552
Intended Use	The TM Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TM Safety Needle is compatible for use with standard luer slip and luer lock syringes. Additionally, after	The TERUMOO SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible	U&U Sterile Hypodermic Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration

	withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle-stick.	for use with standard luer slip and luer lock syringes. Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.	
Principle of Operation	Normal	Normal	Normal
Needle Gauge and Length	Various Sizes	Various Sizes	Various Sizes
Lubricant for Needle	Silicone Oil	Silicone Oil	Silicone Oil
Materials **Needle Hub** **Needle** **Needle Sheath**	 PP Stainless Steel PP	 PP Stainless Steel PP	 PP Stainless Steel N.A
Sharps Injury Prevention Features	Needle safety shield	Needle safety shield	N.A
Performances	Conforms to ISO7864	Conforms to ISO7864	Conforms to ISO7864
Biocompatibility	Conforms to ISO10993	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 Test Conclusion:

Non clinical tests were conducted to verify that the subject device met all design specifications and was substantially equivalent to the predicate devices. The non-clinical test results demonstrated that the subject device complies with the following standards:

ISO 7864 Sterile hypodermic needles for single use.
ISO 9626 Stainless steel needle tubing for the manufacture of medical devices
ISO 23908 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

8. Conclusion:

The intended use, materials, performance, and operational features of the TM safety needle are substantially equivalent to the predicate devices.

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