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.
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Contract Manufacturer Name: ANHUI TIANKANG MEDICAL PRODUCTS CO., LTD.
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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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