August 6, 2020

Anhui Tiankang Medical Technology Co., Ltd.
Bai Baodong
RA Manager
No.228 Weiyi Road, Economic Development Zone
Tianchang City
Anhui China 239300

Re: K191644
Trade/Device Name: TK Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 7, 2020
Received: July 7, 2020

Dear Bai Baodong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191644

Device Name
TK Safety Needle

Indications for Use *(Describe)*
TK Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TK 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.

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.***

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## K191644 510(K) Summary

**Date revised: 8.5.2020**

### 1. Submitter Name and Address:

**Owner** Name: Anhui Tiankang Medical Technology Co.,Ltd.
Address: No.228 Weiyi Road .Economic Development Zone ,Tianchang City.Anhui,China
Contactor Name: Bai Baodong
TEL: +86-550-7309187
E-mail: tkquality@126.com

**Manufacturer** Name: Anhui Tiankang Medical Technology Co.,Ltd
Address: No.228 Weiyi Road ,Economic Development Zone ,Tianchang City,Anhui,China

**US Agent**:
US Agent: James H . Liao
Address: 6775 Verde Ridge Rd Rancho Palos Verdes, CA 90275
TEL: 310 3758169 Ext
Email: James@Sino2us.Com

### 2. Submission Devices Information:

Trade/Proprietary Name: TK Safety Needle
Classification name: Needle, Hypodermic, Single Lumen
Class: II.
Panel:80.
Product codes: FMI
Regulation number: 21CFR880.5570
Submission Type: 510(K)

### 3. Predicate Device Information:

Company 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
Trade Name: TM Safety Needle
510(K) Number: K142765

### 4. Device Description:

**TK Safety Needle**
The TK 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.

## Table 1_Subject device

| Ref Number | Model Number | Description | Length | Size |
|---|---|---|---|---|
| TKSN001 | TKSN | Safety Hypodermic Needle | 1/2 to 1” | 30G |
| TKSN002 | TKSN | Safety Hypodermic Needle | 1/2 to 1” | 29G |
| TKSN003 | TKSN | Safety Hypodermic Needle | 1/2 to 1” | 28G |
| TKSN004 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 27G |
| TKSN005 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 26G |
| TKSN006 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 25G |
| TKSN007 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 24G |
| TKSN008 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 23G |
| TKSN009 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 22G |
| TKSN010 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 21G |
| TKSN011 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 20G |
| TKSN012 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 19G |
| TKSN013 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 18G |
| TKSN014 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 17G |
| TKSN015 | TKSN | Safety Hypodermic Needle | 1 to 1 1/2” | 16G |

## Table 2_Predicate device

| Ref Number | Model Number | Description | Length | Size |
|---|---|---|---|---|
| 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. Indications for use:**

TK Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TK 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. Comparison of technological characteristics with the predicate:**

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.

## TK Safety Needle Comparison Table

| **Element of Comparison** | **SUBJECT DEVICE** | **PREDICATE DEVICE K142765** |
|---|---|---|
| **Intended Use** | The TK Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TK 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. | 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. |
| **Principle of Operation** | Normal | Normal |
| **Needle Gauge and Length** | Refer to table 1 | Refer to table 2 |
| **Lubricant for Needle** | Silicone Oil | Silicone Oil |
| **Adhesive** | Epoxy Sizes | Epoxy Sizes |
| **Needle Hub Colors** | Various Colors | Various Colors |
| **Tip configuration** | Bevel | Bevel |
| **Wall Type** | From 16G to 23G: thin wall<br>From 24G to 30G：<br>regular wall | Unknown |

| | | |
|---|---|---|
| **Materials**<br>**Needle Hub**<br>**Needle**<br>**Needle Sheath** | Polypropylene<br>Stainless Steel<br>Polypropylene | Polypropylene<br>Stainless Steel<br>Polypropylene |
| **Sharps injury Prevention Features** | Needle safety shield | Needle safety shield |
| **Performance** | Conforms to ISO 7864 | Conforms to ISO 7864 |
| **Biocompatibility** | Conforms to ISO 10993 | Conforms to ISO 10993 |
| **Labeling** | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 |

## 7. Non-Clinical Testing

Functional Performance Testing

The sterile, single lumen hypodermic needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

ISO 7864:2016, Sterile hypodermic needles for single use

- Fragmentation test (ISO 7864: 2016)
- Determination of flow rate(ISO 7864: 2016)
- Penetration force and drag force(ISO 7864: 2016)
- Bonding strength(ISO 7864: 2016)

ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications-part 7: Connectors for intravascular or hypodermic applications

- Leakage by pressure decay(ISO80369-7:2016)
- Falling drop positive-pressure liquid leakage(ISO80369-7:2016)
- Subatmospheric-pressure air leakage(ISO80369-7:2016)
- Stress cracking(ISO80369-7:2016)
- Resistance to separation from axial load(ISO80369-7:2016)
- Resistance to separation from unscrewing(ISO80369-7:2016)
- Resistance to overriding(ISO80369-7:2016)

ISO 9626 Stainless Steel Needle Tubing for the Manufacture of medical Devices

ISO 23908 Sharps Injury protection-Requirements and test methods

Sharps injury testing per FDA guidance *Medical Devices with Sharps Injury Prevention Features*

Sterility

EO sterilization testing conducted(ISO11135:2014,ISO11607-1:2006,ISO11607:2006,ISO10993-7:2008)

Biocompatibility Testing(ISO10993-1:2018)

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following testing was conducted:

Cytotoxicity(ISO10993-5:2017)

Sensitization(ISO10993-10:2017)

Irritation(ISO10993-10:2017)

Acute Systemic Toxicity(ISO10993-11:2017)

Pyrogenicity(ISO10993-4:2017)

Hemocompatibility(ISO10993-4:2017)

Particulate matter testing(USP<788>)

## 8. Clinical Testing

N/A

## 9. Conclusions

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