



Zhejiang Kangkang Medical-Devices CO., Ltd.  
Chun Guo  
Quality Manager  
Longwang Industrial District, Chumen Town  
Yuhuan, Zhejiang 317605  
China

Re: K213535

Trade/Device Name: Sterile Safety Hypodermic Needles for Single Use  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: Class II  
Product Code: FMI  
Dated: March 23, 2022  
Received: April 12, 2022

Dear Chun Guo:

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](mailto: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

## Indications for Use

510(k) Number (if known)

K213535

Device Name

Sterile Safety Hypodermic Needles for Single Use

Indications for Use (Describe)

The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for medical purpose. 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 needlesticks.

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.

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## K213535 510(k) summary

### I Submitter

Device submitter: Zhejiang Kangkang Medical-Devices CO., Ltd.  
Longwang Industrial District, Chumen Town, Yuhuan, Zhejiang,  
317605, China

Contact person: Chun Guo  
General Manager  
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Email: guochun@vip.126.com

Date: 5/13/2022

### II Device

Trade Name: Sterile Safety Hypodermic Needles for Single Use  
Common Name: Hypodermic Single Lumen Needle  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Device Class: Class II  
Product code: FMI

### III Predicate Devices

Trade name: TK Safety Needle  
Common name: Hypodermic Single Lumen Needle  
Classification: Class II, 21 CFR 880.5570  
Product Code: FMI  
Premarket Notification: K191644  
Manufacturer: Anhui Tiangkang Medical Technology Co., Ltd

### IV Device description

The Sterile Safety Hypodermic Needles for Single Use are composed of a hypodermic needle with a needle safety shield attached to the needle hub, which can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks. The device is compatible for use with standard luer slip and luer lock syringes. The Sterile Safety Hypodermic Needles for Single Use is for

single use only. It is provided sterile. The sterilization method is EO sterilization and the sterilization assurance level is 10<sup>-6</sup>.

Connection type	Luer										
Color of needle hub	Yellow	Medium Grey	Brown	Orange	Middle Purple	Deep blue	Black	Deep green	Yellow	Cream	Pink
Gauge	30G	27G	26G	25G	24G	23G	22G	21G	20G	19G	18G
Length of needle tube	1/2"		1/2"、 5/8"、 1"	5/8"、 1"	5/8"、 1"	1"、 1 1/4"、 1 1/2"					
Length of needle covers (mm)	12.5		12.5、 16、 25	16、25	16、 25	25、 32、 38					
Color of needle covers	Transparent										
Type of wall	Normal wall and thin wall										
Blade angle	Short bevel and long bevel										

#### V Indications for use

The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for medical purpose. 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 needlesticks.

#### VI Comparison of technological characteristics with the predicate devices

The Sterile Safety Hypodermic Needles for Single Use have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Sterile Safety Hypodermic Needles for Single Use and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K191644	Comments
Indications for use	The Sterile Safety Hypodermic Needles for Single Use are intended for use in the aspiration and injection of fluids for medical purpose. The device 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 needlesticks.	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.	Comment 1

Device feature	Subject Device		Predicate Device K191644		Comments
Class	CLASS II		CLASS II		Identical
Principle of operation	Normal		Normal		Identical
Needle gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 30G		16G、 17G、 18G、 19G、 20G、 21G、 22G、 23G、 24G、 25G、 26G、 27G、 28G、 29G、 30G		Substantially equivalent Comment 2
Length	, 5/8", 1", 1 1/4", 1 1/2"		1/2" to 1 1/2"		
Type of wall	Thin wall and normal wall		From 16G to 23G: thin wall From 24G to 30G: regular wall		
blade angle	Short bevel and long bevel		Bevel		
main structure and materials	Needle hub	Polypropylene	Needle Hub	Polypropylene	Identical
	Needle tube	Stainless steel	Needle	Stainless Steel	
	Protective cover	Polypropylene	Needle Sheath	Polypropylene	
Needle hub Colors	Various Colors		Various Colors		Identical
Sharps injury Prevention Features	Needle safety shield		Needle safety shield		Identical
Lubricant for Needle	Silicone Oil		Silicone Oil		Identical
Performance specifications	Conforms to ISO 7864		Conforms to ISO 7864		Identical
Sterilization	EO sterilization		EO sterilization		Identical
Biocompatibility	Conforms to ISO 10993		Conforms to ISO 10993		Identical
Labeling	Meet the requirements of 21 CFR Part 801		Meet the requirements of 21 CFR Part 801		Identical

Discussion:

Comment 1

Minor rewording of the Intended use statement has been made. However, the general purpose of the device and its function remain unchanged. The subject devices are also compatible with standard slip tip and luer lock syringes, even

though the IFU does not exclusively say that. The minor rewording of the Intended use statement does not raise different questions of safety and effectiveness.

#### Comment 2

The subject device's needle gauge and needle length are smaller than the predicate device's needle gauge range of 16G to 30G and length range of 1/2" to 1 1/2". The type of wall and needle bevel are different from the predicate device. However, this difference is just in dimension. Different needle specification will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences were addressed through ISO 7864, ISO 9626 and ISO 80369-7. Therefore, the differences on needle length, gauge, wall type and bevel does not affect substantially equivalence on safety and effectiveness.

### **VII Performance data**

The following performance data were provided in support of the substantial equivalence determination.

#### **Biocompatibility testing**

Biocompatibility of the Sterile Safety Hypodermic Needles for Single Use were evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device – Blood path indirect" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended:

Cytotoxicity	ISO 10993-5: 2009
Skin sensitization	ISO 10993-10: 2010
Hemolysis	ISO 10993-4: 2017
Intracutaneous reactivity	ISO 10993-10: 2010
Acute systemic toxicity	ISO 10993-11: 2017
Pyrogenicity	ISO 10993-11: 2017

Particulate matter testing was conducted in accordance with Method 1 of USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

#### **Sterilization and shelf life testing**

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Sterile Safety Hypodermic Needles for Single Use, Sterile Safety Hypodermic Needles for Single Use is determined based on stability study which includes ageing test.

The testing is performed according to the following standards:

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

### **Performance testing**

Performance testing is performed according to the following standards:

- ISO 7864:2016 Sterile Safety Hypodermic Needles for Single Use — Requirements and test methods
- ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 23908 Sharps Injury protection- Requirements and test methods
- Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff

### **VIII Conclusion**

The minor differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The Sterile Safety Hypodermic Needles for Single Use are substantially equivalent to its predicate device (TK Safety Needle) with respect to the indications for use, treatment method and technological characteristics. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.