September 11, 2020

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

Re: K191639
Trade/Device Name: TK Insulin Syringe with/without Safety Retractable Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF
Dated: August 13, 2020
Received: August 13, 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)*
K191639

Device Name
TK Insulin Syringe with/without Safety Retractable Device

Indications for Use *(Describe)*
The TK Insulin Syringe with Safety Retractable Device is a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

The TK Insulin Syringe is a sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

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.

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510(K) Summary: K191639

Date prepared: 09.11.2020

1. Submitter Name and Address:

Owner Name:	Anhui Tiankang Medical Technology Co.,Ltd.
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Contactor Name:	Bai Baodong
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E-mail:	zy@tkmedical.com

Manufacturer -

Name:	Anhui Tiankang Medical Technology Co.,Ltd
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US Agent:

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TEL:	310 3758169 Ext
Email:	James@Sino2us.Com

2.Submission Devices ：

Product Name: TK Insulin Syringe with/without Safety Retractable Device
Classification Name: Syringe, Antistick Piston Syringe
Classification : II.
Product code: MEG and FMF
Submission Type: 510(K) Traditional
Regulation Number: 21 CFR 880.5860

3.Predicate Device ：

K152808
Product Name: U&U Insulin Syringe with/without Safety Retractable Device
Classification name: Syringe, Antistick Piston Syringe
Classification: II
Product Code: MEG and FMF
Regulation No. 21 CFR 880.5860
Review Panel :80

4. Indication for Use

The TK Insulin Syringe with Safety Retractable Device is a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

The TK Insulin Syringe is a sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

5. Device Description:

The TK Insulin Syringe with/without Safety Retractable Device are similar devices except one has a safety feature and the other is a standard insulin syringe.

The TK Insulin Syringe with/without Safety Retractable Device is an integrated needle and piston syringe with an anti-needle-stick mechanism. The mechanism allows clear visualization of the injection site at all times. The mechanism shows the needle is contained within the syringe barrel. After standard techniques for injection, the plunger is withdrawn and snapped off which renders the needle unusable and prevents accidental needle sticks. The used syringe is then discarded into a sharp's container.

The subject devices are sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.

The TK Insulin Syringe with/without Safety Retractable Device will be available in numerous sizes and combinations in the following table.

Ref Number	Model Number	Description	Size
TKIS001	TKIS	Insulin Syringe	0.3cc/ml Needle 27G ×1/2" 0.3cc/ml Needle 28G ×1/2" 0.3cc/ml Needle 29G ×1/2" 0.3cc/ml Needle 30G ×1/2" 0.3cc/ml Needle 31G ×3/8"
TKIS002	TKIS	Insulin Syringe	0.5cc/ml Needle 27G ×1/2" 0.5cc/ml Needle 28G ×1/2" 0.5cc/ml Needle 29G ×1/2" 0.5cc/ml Needle 30G ×1/2"

			0.5cc/ml Needle 31G ×3/8”
TKIS003	TKIS	Insulin Syringe	1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2” 1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8”
TKSIS001	TKSIS	Insulin Syringe with Safety Retractable Device	0.5cc/ml Needle 27G ×1/2” 0.5cc/ml Needle 28G ×1/2” 0.5cc/ml Needle 29G ×1/2” 0.5cc/ml Needle 30G ×1/2” 0.5cc/ml Needle 31G ×3/8”
TKSIS002	TKSIS	Insulin Syringe with Safety Retractable Device	1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2” 1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8”

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.

The main components of a TK insulin syringe with a safety retractable device are manufactured to the same or similar specifications as the said assertion device. The intended use, basic design, function, and materials of the predicate device are identical to or similar to the predicate device. The difference between the subject device and the predicate does not affect the safety and effectiveness of the subject device because the evaluation is conducted using industry consensus standards and based on the performance requirements of the device. Therefore, different technical features do not introduce new safety and effectiveness issues and are essentially equivalent to predicate devices.

Comparison Table

Element of Comparison	Submission Device	Predicate Device K152808	Comment
Intended Use	The TK Insulin Syringe with Safety Retractable Device is a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse. The TK Insulin Syringe is a sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.	The U&U Insulin Syringe with Safety Retractable Device is a sterile, single-use, disposable and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse. The U&U Insulin Syringe is a sterile, single-use, disposable and non-reusable, insulin syringe intended for injection of U-100 insulin into the body.	Same
Principle of Operation	Normal	Normal	Same
Syringe Capacity	TK Insulin Syringe: 0.3cc/ml Needle 27G ×1/2” 0.3cc/ml Needle 28G ×1/2” 0.3cc/ml Needle 29G ×1/2” 0.3cc/ml Needle 30G ×1/2” 0.3cc/ml Needle 31G ×3/8” 0.5cc/ml Needle 27G ×1/2” 0.5cc/ml Needle 28G ×1/2” 0.5cc/ml Needle 29G ×1/2” 0.5cc/ml Needle 30G ×1/2”	U&U Insulin Syringe 0.3cc/ml Needle 27G to 31G 0.5cc/ml Needle 27G to 31G 1cc/ml Needle 27G to 31G U&U Insulin Syringe with Safety Retractable Device: 1cc/ml only Needle 27G to 31G	Different Because there are many customers in our market who need 0.5cc/ml, which indicates that customers have demand for this specification, we have added 0.5cc/ml in the syringe

	0.5cc/ml Needle 31G ×3/8” 1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2” 1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8” TK Insulin Syringe with Safety Retractable Device: 0.5cc/ml Needle 27G ×1/2” 0.5cc/ml Needle 28G ×1/2” 0.5cc/ml Needle 29G ×1/2” 0.5cc/ml Needle 30G ×1/2” 0.5cc/ml Needle 31G ×3/8” 1cc/ml Needle 27G ×1/2” 1cc/ml Needle 28G ×1/2” 1cc/ml Needle 29G ×1/2” 1cc/ml Needle 30G ×1/2” 1cc/ml Needle 31G ×3/8”		capacity. Adding 0.5mL does not affect the safety and effectiveness of the subject device and is verified by non-clinical testing listed in Section 7.
Nozzle Type	N.A	N.A	Same
Lubricant for Barrel	Silicone Oil	Silicone Oil	Same
Barrel Transparency	Transparent and Clear	Transparent and Clear	Same
Gradations Legibility	Legible	Legible	Same
Materials **Barrel** **Plunger** **Piston**	 PP PP Rubber	 PP PP Rubber	Same

Lubricant for Barrel **Needle Hub** **Needle** **Needle Sheath**	HC-SS36 PP Stainless PP	HC-SS36 PP Stainless PP	
Needle Gauge and Length	Various Sizes	Various Sizes	Same
Lubricant for Needle	Silicone Oil	Silicone Oil	Same
TK Insulin Syringe with Safety Retractable Device: Sharps Injury Prevention Features	Manual Retractable Conforms to ISO 23908	Manual Retractable Conforms to ISO 23908	Same
Performances	Conforms to ISO7864 ISO8537	Conforms to ISO7864 ISO8537	Same
Biocompatibility	Conforms to ISO10993(Part 1: Evaluation and testing, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation and delayed-type hypersensitivity, Part 11: Tests for systemic toxicity, Tests for Bacterial endotoxins, Tests for Pyrogenicity) Conforms to USP <788>: Particulate Matter for injection	Conforms to ISO10993(Part 1: Evaluation and testing, Part 4: Selection of tests for interactions with blood, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation and delayed-type hypersensitivity, Part 11: Tests for systemic toxicity) Conforms to USP <788>: Particulate Matter for injection	Same
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

7.Non-Clinical Tests performed on the subject device:

The proposed devices were tested per the following standards, to evaluate its performance.

- ISO 8537: 2016 Third edition, Sterile single-use syringes, with or without needle, for insulin.
- ISO 7864:2016 Fourth edition, Sterile hypodermic needles for single use-Requirements and test method.

For the TK Insulin Syringe with Safety Retractable Device Only:

- ISO 9626:2016 Second edition 2016-08-01 Stainless steel needle tubing for manufacture of medical device-Requirements and test method.
- ISO 23908:2011 First edition 2011-06-11 Sharps Injury Protection-Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.
- Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features:

Biocompatibility

Conforms to ISO10993. The TK Insulin Syringe with/without Safety Retractable Device is classified as prolonged, external communicating device, indirect blood contact with the following endpoints:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Acute systemic toxicity
- Material mediated pyrogenicity
- Subacute/Subchronic toxicity
- Indirect hemolysis
- USP 788

- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- USP <788>: Particulate Matter for injection

8. Conclusions:

The TK Insulin Syringe with/without Safety Retractable Device is substantially equivalent to the U&U Insulin Syringe with Safety Retractable Device. The materials, performance, and operational features of both the subject device and the predicate devices are substantially equivalent.