January 6, 2020

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

Re: K191642
Trade/Device Name: TK Sterile Piston Syringe without Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 28, 2019
Received: December 4, 2019

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
Acting 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)*
K191642

Device Name
TK Sterile Piston Syringe without Needle

Indications for Use *(Describe)*
TK 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)

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary: K191642

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: 05.16.2019

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: tkaualitv@126.com

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

US Aaent:
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 Sterile Piston Syringe without Needle
Regulation: 21CFR 880.5860
Classification name: Piston Syringe.
Class: II.
Product codes: FMF
Submission Type: 510(K)
Panel: 80.

3. Predicate Devices 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: U&U Sterile Piston Syringe without Needle
510(K) Number: K132553

♦Devices Description:

4.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 is labeled Non-Pyrogenic. The device is intended for single use only.

Ref Number	Model	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

Ref Number	Model	Description	Size
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.Indications for use:

TK Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/ injection.

6. Comparison of technological characteristics with the predicate:

The following table provides a comparison to the predicate device:

Sterile Piston Hypodermic Syringes Comparison Table

Element of Comparison	SUBJECT DEVICE	PREDICATE DEVICE K132553
Indication for Use	TK Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/ injection.	The U&U Sterile Piston Syringes is intended for use by health care professionals for general purpose fluid aspiration/ injection.
	The TK Sterile Syringes indications for use is the same as the U&U Sterile Piston Syringes indications for use without any differents.	
Syringe Capacity	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml
Nozzle Type	Luer Slip & Luer Lock	Luer Slip & Luer Lock
Lubricant for Barrel	Dow corning 360 medical fluid silicone oil (0.02mg/cm^2)	Dow corning 360 medical fluid silicone oil (0.02mg/cm2)
Barrel Transparency	Transparent and Clear	Transparent and Clear
Gradations Legibility	Legible	Legible
Materials: Barrel Plunger Piston	 PP PP Polyisoprene Rubber	 PP PP TPE (Rubber)
Performances	Complies with ISO 7886-1:2017 Sterile Hypodermic syringes for single use-Part 1: Syringes for manual use Complies with ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-- Part 7: Connectors for intravascular or hypodermic applications Complies with ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications-- Part 20: Common test methods	Complies with ISO 7886-1:1993 Sterile Hypodermic syringes for single use-Part 1: Syringes for manual use Complies with ISO 594-1:1993 Conical fittings with a 6% (luer) taper for syringes, needles, and certain other medical equipment-Part 1: General requirements Complies with ISO 594-2:1998 Conical fittings with a 6% (luer) taper for syringes, needles, and certain other medical equipment-Part 1: Lock fittings

Sterility	Sterility inspection is based on the methods stipulated in USP<71>, and the results are in line with requirements of USP<71>: No microbial growth was observed.	Sterility inspection is based on the methods stipulated in USP<71>, and the results are in line with requirements of USP<71>: No microbial growth was observed.
Chemical properties	Chemical performances inspection are based on ISO7886-1,inspection items are as follows: Limits for acidity or alkalinity,Limits for extractable metals.Results conform to ISO7886-1.	Chemical performances inspection are based on ISO7886-1,inspection items are as follows: Limits for acidity or alkalinity,Limits for extractable metals.Results conform to ISO7886-1.
Biocompatibility	The biocompatibility evaluation for the TK Sterile Piston Syringe without needle was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and the "Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", June 16, 2016. The syringe of testing included the following tests: Cytotoxicity endotoxin Skin sensitization Hemolysis Intracutaneous reactivity Acute systemic toxicity Pyrogenicity The evaluation of the above testing items meets the requirements.	The biocompatibility evaluation for the TK Sterile Piston Syringe without needle was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The syringe of testing included the following tests: Cytotoxicity endotoxin Skin sensitization Hemolysis Intracutaneous reactivity Acute systemic toxicity Pyrogenicity The evaluation of the above testing items meets the requirements.
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Non Clinical Performance Testing

Functional Performance Testing

General requirements for syringe (ISO 7886-1:2017, ISO 80369-7:2016)

Liquid leakage **(**ISO 7886-1:2017)

Air leakage (ISO 7886-1:2017)

Dead space (ISO 7886-1:2017)

Nozzle Conical fitting (ISO 80369-7:2016)

Leakage by pressure (ISO 80369-7:2016)

Sub atmospheric pressure air leakage (ISO 80369-7:2016)

Stress cracking (ISO 80369-7:2016)

Resistance to separation (ISO 80369-7:2016)

Resistance to unscrewing (ISO 80369-7:2016)

Resistance to overriding (ISO 80369-7:2016)

Bonding strength (ISO 80369-7:2016)

Sterility

EO sterilization testing conducted (ISO 11135: 2014, ISO 11607-1:2006, ISO 11607-2, ISO 10993-7:2008)

Biocompatibility Testing (ISO 10993-1:2018):

Cytotoxicity (ISO 10993-5:2017)

Sensitization (ISO 10993-10:2017)

Irritation (ISO 10993-10:2017)

Acute Systemic Toxicity (ISO 10993-11:2017)

Pyrogenicity (ISO 10993-4:2017)

Hemocompatibility (ISO 10993-4:2017)

Particulate matter testing (USP<788>)

8. Conclusions:

The TK Sterile Piston Syringe without Needle is substantially equivalent to the U&U Sterile Piston Syringe without Needle. The materials, performance, and operational features of both the subject device and the predicate device are substantially equivalent.