August 26, 2020

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

Re: K191640
Trade/Device Name: TK Intravascular Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: July 28, 2020
Received: July 28, 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 Payal Patel
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

510(K) Summary: K191640

Date prepared: 25.08.2020

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, RA Manager

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) 375-8169

Email: James@Sino2us.com

2. Submission Devices Information:

Trade/Proprietary Name: TK Intravascular Administration Set

Common Name: Intravascular administration set

Regulation: 21CFR 880.5440

Regulation name: Set, Administration, Intravascular.

Class: II

Product Codes: FPA

Submission Type: 510(K)

3. Predicate Device Information:

Trade Name: U&U Intravascular Administration Set

510(K) Number: K151151

Common Name: Intravascular administration set

Regulation: 21CFR 880.5440

Regulation name: Set, Administration, Intravascular.

Class: II

Product Codes: FPA

4. Device Description:

TK Intravascular Administration Set

The TK Intravascular Administration Set is a gravity single use device sterilized with Ethylene Oxide gas. It is utilized to administer fluids from a container to a patient's vascular system through a catheter or needle inserted into a vein. The device includes the following components:

Protective cap of spike, Spike, Micron filter, Air inlet, Drip chamber, Fluid filter, Tubing, Slide clamp, Pinch clamp, Flow regulator, Roller, Male luer lock, Stopcock (without needleless luer access valve), 4.0mm Connector, Y-site (access by needle), Rotating luer lock, Back check valve, Luer lock cap. The device is available in multiple configurations listed below.

Ref	Description

Number	
TKIV-F05	Intravascular Administration Set
TKIV-F09	Intravascular Administration Set
TKIV-F10	Intravascular Administration Set
TKIV-F11	Intravascular Administration Set
TKIV-F12	Intravascular Administration Set
TKIV-F13	Intravascular Administration Set
TKIV-F14	Intravascular Administration Set
TKIV-F15	Intravascular Administration Set

5. Indications for use:

TK Intravascular Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

6. Comparison of technological characteristics with the predicate:

TK Intravascular Administration Set is constructed of high grade extruded Polyvinyl Chloride (PVC). The primary components of TK Intravascular Administration Set are manufactured to identical or similar specifications of the predicate device listed above. The intended use, basic design, function and materials used are identical or similar to the predicate device. The differences between the subject device and the predicate device are the y-site in the subject device is a septum while the predicate utilized a needless luer access valve and the material for the stopcock is made of Makrolon for the subject device while the predicate is made of ABS HDPE. These differences in technology do not affect the safety and effectiveness of the subject device because the evaluation were performed using industry consensus standards and evaluated per the performance requirements of the device. Therefore, the different technological characteristics do not raise new questions of safety and effectiveness and is substantially equivalent to the predicate device.

Intravascular Administration Set Comparison Table

Element of Comparison	**SUBJECT DEVICE** **K191640**	**PREDICATE DEVICE** **K151151**	**Comment**
Indications for Use	The TK Intravascular Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	The U&U Intravascular Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.	Same
Mode of Fluid Delivery	Gravity	Gravity	Same
Y-site	Septum	Luer access valve	Different – see discussion above
Tubing	The tubing shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.	The tubing shall be transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.	Same

Materials			
Tubing	PVC	PVC	
Drip chamber	PVC	PVC	
Spike	ABS	ABS	
Protective cap of spike	LDPE	LDPE	
Micron filter	PTFE	PTFE	
Air inlet	PVC	PVC	
Fluid filter	ABS	ABS	Different – see discussion above Biocompatibility testing per ISO 10993-1
Slide clamp	ABS	ABS	
Pinch clamp	POM	POM	
Flow regulator	ABS	ABS	
Roller Clamp	ABS	ABS	
Male luer lock	MABS	MABS	
Stopcock	MAKROLON	ABS HDPE	
4.0mm Connector	MABS	MABS	
Y-site	MABS	MABS	
Rotating luer lock	MABS	MABS	
Back check valve	MABS	MABS	
Luer lock cap	HDPE	HDPE	
Pyrogenicity	<0.5 EU	<0.5 EU	Same
Sterility	Method: by EO Sterility inspection is based on the methods stipulated in USP<71>, and the results are in line with requirements of	Method: by EO Sterility inspection is based on the methods stipulated in USP<71>, and the results are in line with requirements of	Same

	USP<71>: No microbial growth was observed.	USP<71>: No microbial growth was observed.	
Shelf life	3 years	Unknown	Evaluated per ASTM testing
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

7. **Non Clinical Performance Testing**

A. Biocompatibility Testing (ISO 10993-1:2018):

1. Hemocompatibility (ISO 10993-4:2017)
2. Cytotoxicity (ISO 10993-5:2017)
3. Irritation (ISO 10993-10:2017)
4. Sensitization (ISO 10993-10:2017)
5. Acute Systemic Toxicity (ISO 10993-11:2017)
6. Bacterial Endotoxins (ISO 10993-11:2017)
7. Pyrogenicity (ISO 10993-11:2017)
8. Subacute Systemic Toxicity (ISO 10993-11:2017)/ Subchronic Systemic Toxicity Study (ISO 10993-11:2017)

B. Other Non-clinical Test Conducted Using the Following Guidance and Standards:

- FDA Guidance July 2018: Intravascular Administration Sets Premarket Notification Submissions [510(k)]
- ISO 8536-4: 2010, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1(2013)]

- ISO 80369-7: 2016, Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20: 2015, Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 11607-1: 2016, Packaging for terminally sterilized medical device -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2016, Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- 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
- ISO10993-7: 2008, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ISO10993-12: 2012, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials
- ASTM F1980- 2016, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1929- 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88- 2015, Standard Test Method for Seal Strength of Flexible Barrier Materials
- USP 788- Particulate matter for Injection

8. Conclusions:

The Indications for Use, technological characteristics, and performance testing demonstrate that the subject device is substantially equivalent as the predicate device.