Anhui Tiankang Medical Technology Co., Ltd.
Zhang Yong
Management
No.228,Weiyi Road, Economic Development Zone,Tianchang City,
Anhui,China.
Tianchang, Anhui 239300
China

Re: K220204
Trade/Device Name: Disposable Syringe with permanently attached needle, Safety Syringe with permanently attached needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: June 10, 2022
Received: June 21, 2022

Dear Zhang Yong:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220204

Device Name
Disposable Syringe with permanently attached needle;
Safety Syringe with permanently attached needle

Indications for Use *(Describe)*
The Disposable Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential of syringe reuse.

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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510(k) Summary

K220204

I Submitter

Device submitter: Anhui Tiankang Medical Technology Co., Ltd.
No.228, Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China.

Establishment Registration Number
3007590959

Contact person:
Name: Zhang Yong
Title: Management representative
Phone: +86-13705505106
Fax: +86-550-7309158
E-mail: zy@tkmedical.com

Preparation Date**:** July 13, 2022

II Device

Trade Name of Device: Disposable Syringe with permanently attached needle
Safety Syringe with permanently attached needle
Common Name: Piston syringe
Regulation Number: 21CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product code: FMF, MEG
Review Panel: General Hospital

III Predicate Devices

Trade name:	1ml Luer Slip or Luer Lock Syringe Syringe with permanently attached needle (used as Predicate Device) Safety Syringe with permanently attached needle (used as Predicate Device)
Common name:	Piston Syringe and antistick syringe
Classification:	Class II, 21 CFR 880.5860
Product Code:	FMF, MEG

Premarket Notification: K192551
Manufacturer: Jiangsu Caina Medical Co., Ltd.

IV Device description

The proposed Syringes include Disposable Syringe with permanently attached needle and Safety Syringe with permanently attached needle. The Disposable Syringe with permanently attached needle have one kind of product configuration (TKSPN01) and the Safety Syringe with permanently attached needle has two kinds of product configurations (TKSSPN01 and TKSSPN02).

The proposed syringes are available in different combination of syringe volumes and/or needle sizes. The syringe is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6}. The proposed device has a shelf life of three years.

Table 1 specification of proposed device

Model	Syringe Volume	Needle Length	Needle Gauge	Wall type	Needle Bevel
Disposable Syringe with permanently attached needle -TKSPN01	0.5ml; 1ml	3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm); 3/4″ (20mm); 7/8″ (22mm); 1″ (25mm);	23G	TW	LB
			24G	RW	LB
			25G	RW	LB
		3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm); 3/4″ (20mm);	26G	RW	LB
			27G	RW	LB
		3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	28G	RW	LB
		3/10″ (8mm); 3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	29G	RW	LB
			30G	RW	LB
			31G	RW	LB
Safety Syringe with permanently attached needle -TKSSPN01	0.3ml	3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	27G	RW	LB
			28G	RW	LB
		3/10″ (8mm); 3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	29G	RW	LB
			30G	RW	LB
			31G	RW	LB

	0.5ml; 1ml	3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	25G	RW	LB
			26G	RW	LB
			27G	RW	LB
			28G	RW	LB
		3/10″ (8mm); 3/8″ (10mm); 1/2″ (13mm); 5/8″ (16mm);	29G	RW	LB
			30G	RW	LB
			31G	RW	LB
Safety Syringe with permanently attached needle-TKSSPN02	1ml	3/4″ (20mm); 7/8″ (22mm); 1″ (25mm); 1 1/4″ (32mm); 1 1/2″ (38mm);	21G	TW	LB
			22G	TW	LB
			23G	TW	LB
			24G	RW	LB
			25G	RW	LB
		3/4″ (20mm)	26G	RW	LB
		3/4″ (20mm)	27G	RW	LB

V Indications for Use

Disposable Syringe with permanently attached needle

The Disposable Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

Safety Syringe with permanently attached needle

The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential of syringe reuse.

VI Comparison of technological characteristics with the predicate devices

The Disposable Syringe with permanently attached needle and Safety Syringe with permanently attached needle have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The main differences between subject devices and predicate devices are the specification of syringe volume, needle gauge and needle length. The differences between the subject device and the predicate do not affect the safety and effectiveness of the subject device because evaluation is conducted using industry consensus standards and based on the performance requirements of the device. Therefore, these differences do not impact its safety and effectiveness.

Table 6-1 Substantial equivalence discussion for Disposable Syringe with permanently attached needle

Device feature	Subject Device	Predicate Device K192551	Comment
Product	Disposable Syringe with permanently attached needle	Syringe with permanently attached needle	/
Syringe type	Piston syringe	Piston syringe	Same
Indications for use	The Disposable Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.	1ml Luer Slip or Luer Lock Syringe 1ml Luer Slip or Luer Lock Syringe is intended to be connected with the luer slip or luer lock needle and intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. Syringe with permanently attached needle The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. Safety Syringe with permanently attached needle The Safety Syringe with permanently attached	Similar, Comment 1

Device feature	Subject Device	Predicate Device K192551	Comment
		needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.	
Product code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Principle of operation	For Manual Use Only, For Single Use Only	For Manual Use Only, For Single Use Only	Same
Connector Type	Attached needle	Attached needle	Same
Needle gauge	23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Different Comment 2
Needle Length	8mm, 10mm, 13mm, 16mm, 20mm, 22mm, 25mm	8mm, 10mm, 13mm, 16mm, 20mm, 25mm	
Needle wall type	RW, TW	RW, TW	
Needle bevel	11°±2°	11°±2°, 15°±2°	
Syringe Volume	0.5ml, 1ml	0.3ml, 0.5ml, 1ml	

Device feature	Subject Device	Predicate Device K192551	Comment
Main structure and materials	(1) Needle cap (PP) (2) Needle (Stainless Steel 304) (3) Piston (Polyisoprene) (4) Plunger (PP) (5) Barrel (PP)	Syringe with permanently attached needle-type A (1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) piston (Polyisoprene) (4) plunger (PP) (5) barrel (PP) (6) end cap (PP or PE) Syringe with permanently attached needle-type B (1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) piston (Polyisoprene) (4) plunger (PP or ABS) (5) barrel (PP)	Different Comment 3
Single Use	Yes	Yes	Same
Sterilization	EO Sterilization	EO Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Biocompatibility	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Comment 1

The Indications for use of predicated device include the full indication for Use of three products. The 1ml Luer Slip or Luer Lock Syringe does not apply to the proposed device. Compared between Disposable Syringe with permanently attached needle and predicate device (Syringe with permanently attached needle), the IFU is same. And compared between Safety Syringe with permanently attached needle and predicate device (Safety Syringe with permanently attached needle), the IFU is also same. It does not change the intended use.

Comment 2

The needle bevel of subject device (11°±2°) is smaller than the predicate device's bevel range of 11°±2° and 15°±2°. The subject device's 0.5ml and 1ml syringe volume is smaller than the predicated device's syringe volume range of 0.3ml, 0.5ml and 1ml. And the needle gauge and length of subject devices are similar to the predicate device, the difference is just in dimension. Different specification will be selected by physician per patient's condition. This difference does not affect its intended use. In addition, differences were addressed through ISO 7886-1, ISO 7864 and ISO 9626. Therefore, the differences on syringe volume, needle bevel, needle gauge and length do not raise different question of safety and effectiveness.

Comment 3

The configuration of subject device is same as type B of predicate device, and compared with type A, the difference is that the subject device does not have an end cap, however, it has a needle protective cap that protects the needle. This difference does not raise new questions about safety and effectiveness.

The materials of subject device are similar to the predicated device. Biocompatibility testing is performed with the proposed device. Therefore, the differences on configuration and materials do not raise new questions of safety and effectiveness.

Table 6-2 Substantial equivalence discussion for Safety Syringe with permanently attached needle

Device feature	**Subject Device K220204**	**Predicate Device K192551**	**Comment**
Product	Safety Syringe with permanently attached needle	Safety Syringe with permanently attached needle	/
Syringe type	Piston syringe	Piston syringe	Same
Indications for use	The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the	1ml Luer Slip or Luer Lock Syringe 1ml Luer Slip or Luer Lock Syringe is intended to be connected with the luer slip or luer lock needle and intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below	Similar, Comment 1

Device feature	Subject Device K220204	Predicate Device K192551	Comment
	prevention of needle stick injuries and reduce the potential or syringe reuse.	the surface of the skin. Syringe with permanently attached needle The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. Safety Syringe with permanently attached needle The Safety Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin. The Safety sheath of Syringe is designed to aid in the prevention of needle stick injuries and reduce the potential or syringe reuse.	
Product code	MEG	MEG	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Principle of	For Manual Use Only, For	For Manual Use Only, For	Same

Device feature	Subject Device K220204	Predicate Device K192551	Comment
operation	Single Use Only	Single Use Only	
Connector Type	Attached needle	Attached needle	Same
Needle gauge	21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Different Comment 4
Needle Length	8mm, 10mm, 13mm, 16mm, 20mm, 22mm, 25mm, 32mm, 38mm	8mm, 10mm, 13mm, 16mm, 20mm, 25mm	
Needle wall type	RW, TW	RW, TW	
Needle bevel	11°±2°	11°±2°, 15°±2°	
Syringe Volume	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	Same
Main structure and materials	(1) Protective cap (PP) (2) Needle (Stainless Steel 304) (3) Safety mechanism-Connector base (PC) (4) Piston (Polyisoprene) (5) Safety mechanism-Sliding sleeve (PP) (6) Plunger (PP) (7) Barrel (PP)	(1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) safety mechanism (PC) (4) piston (Polyisoprene) (5) safety mechanism (PP) (6) plunger (PP) (7) barrel (PP)	Same
Performance specifications	Complies with ISO 7886-1; ISO 9626 and ISO 7864	Complies with ISO 7886-1; ISO 9626 and ISO 7864	Same
Single Use	Yes	Yes	Same
Sterilization	EO Sterilization	EO Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Biocompatibility	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Contact level: blood path, indirect, limited contact (<24 hours). Conforms to the requirement of ISO 10993 series Standards	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Comment 4

The needle bevel of subject device (11°±2°) is smaller than the predicate device's bevel range of 11°±2° and 15°±2°. And the needle gauge and length of subject devices are similar to the predicate device, the difference is just in dimension. Different 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 and ISO 9626. Therefore, the differences on syringe volume, needle bevel, needle gauge and length do not raise different question of safety and effectiveness.

VII Performance data

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

Biocompatibility testing

Biocompatibility of the Disposable Syringe with permanently attached needle and Safety Syringe with permanently attached needle 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	USP <788>

Sterilization and shelf life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. Bacteria Endotoxin Limit is carried out according to USP42-NF37 <85> Bacterial Endotoxins Test.

The testing is performed according to the following standards:

EO/ECH residue	ISO 10993-7:2008
Bacteria Endotoxin	USP42-NF37 <85>

The shelf life of 3 year is determined based on stability studies which include ageing test according to FDA recognized standard ASTM F1980-16.

Package integrity testing was conducted on the final, packaged, and sterile devices after environmental conditioning and simulated transportation. All packaging deemed acceptable for protection of product and sterility maintenance.

The testing is performed according to the following standards:

Seal strength	ASTM F88/F88M-15
Blue Dye Penetration	ASTM F 1929-2015
Seal Integrity (Visual Inspection)	ASTM F 1886/ F 1886M-16

Performance testing

Performance testing is performed according to the following standards:

- ISO 7886-1: 2017, Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- ISO 7864: 2016, ISO 9626:2016, Stainless Steel Needle Tubing For The Manufacture of Medical Devices.
- ISO 9626:2016, Stainless Steel Needle Tubing for The Manufacture of Medical Devices.
- ISO 6009:2016, Hypodermic needles for single use – Colour coding identification
- ISO 23908:2011 Sharps injury protection - Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The Disposable Syringe with permanently attached needle and Safety Syringe with permanently attached needle are substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, effective and performs as well as the legally marketed device.