October 2, 2025

Ningbo Tianyi Medical Appliance Co., Ltd.
% Mike Gu
RA Manager
Suzhou Device Innovation Medical Consulting Co., Ltd
Room 1001, Building 19, No. 3188 Renming Road
Suzhou, Jiangsu 215031
China

Re: K251442
Trade/Device Name: TIANYI Extracorporeal Blood Tubing Set (TY-NDEO-A1)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: FJK
Dated: September 2, 2025
Received: September 2, 2025

Dear Mike Gu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251442

Please provide the device trade name(s).

TIANYI Extracorporeal Blood Tubing Set (TY-NDEO-A1)

Please provide your Indications for Use below.

TIANYI Extracorporeal Blood Tubing Set is a sterile,single use, disposable indicated for use with a prescribed hemodialyzer.
TIANYI Extracorporeal Blood Tubing Set is intended for acute and chronic hemodialysis therapy.
TIANYI Extracorporeal Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K2 and T hemodialysis Machines.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submission: K251442

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Sponsor Identification

Ningbo Tianyi Medical Appliance Co., Ltd.
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Date prepared May 9, 2025

2. Designated Submission correspondent

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3. PROPOSED DEVICE

Trade Name:TIANYI Extracorporeal Blood Tubing

Classification Name: Set, Tubing, Blood, With and Without Anti-Regurgitation Valve

Classification: II

Product Code: FJK

Regulation Number: 876.5820

Review Panel: Gastroenterology/Urology

4. PREDICATE DEVICE

Device Name: CombiSet Hemodialysis Blood Tubing Set K213992

Regulation number: 21 CFR 876.5820 Regulation

Class: Class II

Product Code: FJK

5. DEVICE DESCRIPTION

The proposed device, TIANYI Extracorporeal Blood Tubing Set, is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. The device is intended for acute and chronic hemodialysis therapy. The TIANYI Extracorporeal Blood Tubing Set is intended to be used with Fresenius Medical Care 2008 Series K, K^2 and T Hemodialysis Machines. The proposed device is provided sterile and for single use. It is for Rx use.

TIANYI Extracorporeal Blood Tubing Set is composed of two parts, the Arterial Line (AL) and the Venous Line (VL). Arterial Line is coded red, and Venous Line is coded blue.

The device consists of Dialyzer connector, Dialyser connector cap, Main tubing, Pump segment, Pump connectors, Arterial Chamber, Venous Chamber, Filter of venous chamber, Chamber caps, Sampling port, Clamps, Patient end (Male rotating hub luer and Rotatable threaded collar), Female luer lock, Recirculation connector, Infusion line, Pressure monitoring line, Transducer protector, Heparin line, Heparin female luer lock, Female luer cap, T connector, and priming set.

Table 1 TIANYI Extracorporeal Blood Tubing Set specification and parameters

Model	Length of Arterial Line (mm)	Length of Venous Line (mm)	Total Length (mm)	Pump Segment OD (mm)	Priming Volume (ml)
TY-NDEO-A1	3635	2770	6405	12	128

The proposed device is sterilized by Ethylene Oxide (EO) to achieve a SAL 10^{-6} level and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 2 years.

6. INDICATIONS FOR USE

TIANYI Extracorporeal Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer.
TIANYI Extracorporeal Blood Tubing Set is intended for acute and chronic hemodialysis therapy.
TIANYI Extracorporeal Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T hemodialysis Machines.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2: Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K213992	Remark
Device Name	TIANYI Extracorporeal Blood Tubing Set	CombiSet Hemodialysis Blood Tubing Set	/
Device Class	II	II	Same
Product Code	FJK	FJK	Same

Regulation Number	21 CFR 876.5820		21 CFR 876.5820	Same
Indications for Use	TIANYI Extracorporeal Blood Tubing Set is a sterile,single use, disposable indicated for use with a prescribed hemodialyzer. TIANYI Extracorporeal Blood Tubing Set is intended for acute and chronic hemodialysis therapy. TIANYI Extracorporeal Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T hemodialysis Machines.		The Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. For use with a compatible hemodialyzer, as per the labeling. The Blood Tubing Set is intended for acute and chronic hemodialysis therapy. The Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T Hemodialysis Machines.	Same
Compatible Hemodialysis Delivery System	TIANYI Extracorporeal Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T hemodialysis Machines.		The Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T Hemodialysis Machines.	Same
Feature	Pre-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device		Pre-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Same
Main Configuration	Arterial Line with Attached Priming Set		Arterial Line with Attached Priming Set	Same
	Venous Line		Venous Line	Same
	T Connector		Saline T	Same
	Arterial Chamber		Arterial Chamber	Same
	Venous Chamber		Venous Chamber	Same
	Pressure Monitoring Line		Monitor Line	Same
	Infusion Line		“Pigtail” Access Site	Same
	Heparin Line		Heparin Access Site	Same
	Transducer Protector (TP)		Transducer Protector (TP)	Same
	Sampling Port		Septum Injection Site	Same
	Y connector with injection site		Y-Injection Site	Same
	Spike		Saline Spike	Same
Labeling	21 CFR part 801		21 CFR part 801	Same
Performance	Conforms to ISO 8637-2:2018 ISO 80369-7:2021		Conforms to ISO 8638:2010 ISO 80369-7:2016	Same
Physical Performance	Length of arterial Line (mm)	3635	3632	Different

	Length of venous Line (mm)	2770	2769	
	Main tubing I.D. (mm)	4.2	4.57	
	Main tubing O.D. (mm)	6.6	6.73	
	Priming Volume (mL)	128	142	
	Positive pressure (mmHg)	500	500	Same
	Negative Pressure (mmHg)	-300	-300	
	Blood Flow limits(ml/min)	600	600	
Materials	Tubing and Components: Polyvinylchloride (PVC) Polypropylene (PP) Polyethylene (PE) Acrylonitrile-Butadiene-Styrene Copolymer Medical silicone Isoprene rubber Transducer Protector: Polyvinylchloride (PVC) Polytetrafluoroethylene Bonding Solvents: Cyclohexanone Butanone		Tubing and Components: Polyvinylchloride (PVC) Polypropylene (PP) Polyethylene (PE) Methylmethacrylate acrylonitrile butadiene styrene (MABS) Polyisoprene Transducer Protector: Polypropylene (PP) Polytetrafluoroethylene on Polyester Bonding Solvents: Cyclohexanone TetraMEK (95% Tetrahydrofuran/5% MEK)	Different
Tensile Test	Pass		Pass	Same
Repeated Closing	Pass		Pass	Same
Endurance Test	Pass		Pass	Same
Spike Flow Rate	Pass		Pass	Same
Spike Leakage-free	Pass		Pass	Same
Spike Insertion Force	Pass		Pass	Same
Spike Separation Force	Maximum value: 3.13N Minimum value:2.34N Average value: 2.67N		Maximum value: 6.47N Minimum value:2.32N Average value: 4.08N	Different
Fluid Level Detection	Pass		Pass	Same
Filter Retention	Pass		Pass	Same
Transducer Protector Viral Retentiveness	Pass		Pass	Same
Biocompatibility	Conforms to ISO 10993 Series standard		Conforms to ISO 10993 Series standard	Same
Sterilization	SAL (10^{-6})		SAL (10^{-6})	Same

Different Analysis- Physical performance (Length of arterial line & venous Line, Main tubing diameter, Priming Volume)

The physical specification of arterial and venous tubes of proposed device is different to that of the predicate device. The differences on the length of arterial and venous tubes, and on the main tubing diameter lead to the difference on the priming volume. Differences in the tubing length and priming volume may impact the mechanical and performance characteristics of device. The bench tests such as ISO 8637-2 tests and simulated operation test were conducted to approve that the proposed device meet the requirements of mechanical and performance characteristics. Therefore, the differences in length of arterial line & venous line, main tubing diameter and priming volume will not lead to new safety and effectiveness problems.

Different analysis -Material difference

The major parts of the proposed device and the predicate device share the same raw material such as PVC, PE, PP etc., but they have differences in some components in respect of material application. The difference in materials may impact the biocompatibility and mechanical performance of the device. For biocompatibility, the device is categorized as externally communicating, circulating blood and long-term contact. Extractables assessment, toxiciological risk assessment and biocompatibility tests have been conducted to demonstrate that the device is biocompatible. Additionally, bench tests such as ISO 8637-2 tests, ISO80369-7 tests, endurance test, tensile test, repeated closing test, transducer protector viral retentiveness test were carried out to prove that the proposed device meets the requirements of mechanical and performance characteristics. Therefore, the differences in materials will not lead to new safety and effectiveness problems.

Different analysis - Spike Separation Force

Comparison performance test indicated that the average separation force of spike, a component of the priming set, of the proposed device was significantly lower than that of the predicate device. The lower separation force may facilitate the removal of the spike after the priming process is completed, which contributes to easier operability in clinical use. While low separation force may lead to connection failure and unexpected spike detachment during the priming process, thereby causing leakage of saline. Leakage test was conducted on the spike of the proposed device, which demonstrated that the spike met the performance requirement for leakage-free connection. Therefore, the difference in spike separation force will not lead to new safety and effectiveness problems.

8. PERFORMANCE DATA

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. For full titles of the standards and guidance used, see below. The tests performed on the proposed device include:

Tensile Strength Test

The tensile strength test was performed on proposed device. The test result demonstrated that any connections between the components of the proposed device shall withstand a static tensile force. This test is an internal test.

Repeated closing test

The repeated closing test was performed on proposed device. The test result demonstrated that the device clamp can successfully occlude the blood tubing and the tubing meets the requirement of resisting kinking after repeated clamping. This test is an internal test.

Endurance Pump Test

The endurance pump test was performed on proposed device. The test result demonstrated that the proposed device is able to meet the endurance requirements. This test is an internal test.

Spike performance test

The spike performance test was performed on proposed device. The test result demonstrated that the spike of priming set is able to meet the performance requirements. This test is an internal test.

Level detection test

Level detection test was performed on proposed device. The test result demonstrated that the venous chamber of the bloodline interfaces correctly with the intended hemodialysis machine. This test is an internal test.

Filter retention test

The filter retention test was performed on proposed device. The test result demonstrated the blood filter meet the requirement of remaining in assembly position under set pressure and flow rate conditions.

Transducer protector viral retentiveness test

Transducer protector viral retentiveness test was performed on proposed device. The test result demonstrated the transducer protector can meet the performance requirement of preventing the passage of bacteriophage (Φ X174) from the patient side to the machine side

Stimulated Operation Test

The stimulated operation test was performed on proposed device. The test result demonstrated that the proposed device has good compatibility performance in hemodialysis treatment conditions with specific hemodialysis delivery system. This test is an internal test.

The proposed device complies with the following standards and guidance:

- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- 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
- ISO 10993-17:2023 Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18:2020/Amd 1:2022 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process — Amendment 1: Determination of the uncertainty factor
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
- ASTM F2382-18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
- ISO 11135-1: 2014/A1:2018 Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F88/F88M-23: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-23: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM D4169-2023 Standard Practice for Performance Testing of Shipping Containers and Systems
- USP -NF <85> Bacterial Endotoxins Test
- ANSI/AAMI/ST72:2019 Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing
- USP-NF <151> Pyrogen Test
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 8637-2:2018 Extracorporeal systems for blood purification - Part 2: Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters

9. CLINICAL DATA

No clinical study is included in this submission.

10. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K213992.