September 6, 2021

Jiangxi Sanxin Medtec Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K202796
Trade/Device Name: SANSIN Tubing Sets for Hemodialysis
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FJK
Dated: August 4, 2021
Received: August 10, 2021

Dear Diana Hong:

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,

Glenn B. Bell, Ph.D.
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

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)*
K202796

Device Name
SANSIN Tubing Sets for Hemodialysis

Indications for Use *(Describe)*
The SANSIN Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202796

1. Date of Preparation: 08/04/2021

2. Sponsor Identification

**Jiangxi Sanxin Medtec Co., Ltd.**
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Christina Wu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: SANSIN Tubing Sets for Hemodialysis
Common Name: Blood Tubing Sets
Models: HDJ, HDK, HDL, HDM, HDN.

Regulatory Information

Classification Name: Set, Tubing, Blood, With and Without Anti-Regurgitation Valve
Classification: II
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Indications for Use:

The SANSIN Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge.

Device Description

The propose device, SANSIN Tubing Sets for Hemodialysis, is used to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The proposed devices are provided sterile and single use.

The proposed device is intended to be used with Fresenius 2008K Home Hemodialysis manufactured by Fresenius Medical Care North America, which is a hemodialysis delivery system being submitted to FDA for premarket notification (K124035).

The proposed device mainly consists of two tubes, which are arterial line with certain components in red and venous line with certain components in blue, as well as accessories such as priming piece, drain bag, priming needle, fluid replacement tube, connecting tube, monitor and transducer protector.

The proposed devices are available in various specifications. Based on the different volume of air capture chamber, there are five models HDJ, HDK, HDL, HDM and HDN. For the detail information of these five models, please see the below Table 1.

Table 1

| Item | HDJ | HDK | HDL | HDM | HDN |
|---|---|---|---|---|---|
| Volume of air capture chamber | Different | Different | Different | Different | Different |
| Diameter and Length of air capture chamber in arterial Line | Different | Different | Different | Different | Different |
| Diameter and Length of air capture chamber in venous Line | Different | Different | Different | Different | Different |
| Length of arterial Line (mm) | Different | Different | Different | Different | Different |
| Length of venous Line (mm) | Different | Different | Different | Different | Different |

| | | | | | |
|---|---|---|---|---|---|
| Diameter of arterial Line (mm) | Same | Same | Same | Same | Same |
| Diameter of venous Line (mm) | Same | Same | Same | Same | Same |
| Priming Volume (mL) | Different | Different | Different | Different | Different |
| Positive pressure (mmHg) | Same | Same | Same | Same | Same |
| Negative Pressure (mmHg) | Same | Same | Same | Same | Same |
| Blood Flow limits (ml/min) | Same | Same | Same | Same | Same |
| Length of Fluid replacement tube | Same | Same | Same | Same | Same |
| Diameter of Fluid replacement tube | Same | Same | Same | Same | Same |

The proposed devices are provided in sterile condition, it is subject to EO sterilization prior to release to achieve a Sterility Assurance Level (SAL) of $10^{-6}$.

5. Identification of Predicate Device

510(k) Number: K161582
Product Name: DORA Tubing Sets for Hemodialysis
Manufacturer: Bain Medical Equipment (Guangzhou) Co., Ltd

6. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics

| ITEM | Proposed Device<br>SANSIN Tubing Sets for Hemodialysis | Predicate Device<br>DORA Tubing Sets for Hemodialysis<br>K161582<br>BAIN-BL-001E | Remark |
|---|---|---|---|
| Device Class | II | II | Same |
| Product Code | FJK | FJK | Same |
| Regulation Number | 21 CFR 876.5820 | 21 CFR 876.5820 | Same |

| | | | |
|---|---|---|---|
| Indications for Use | The SANSIN Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge. | The DORA Tubing Sets for Hemodialysis are single-use sterile medical devices intended to connect the patient to the hemodialyzer and the hemodialysis delivery system in hemodialysis treatment. The compatibility of available configurations is the responsibility of the physician/clinician in charge. | Same |
| Compatible Hemodialysis Delivery System | The hemodialysis delivery system which is compatible with the product is Fresenius 2008K Home Hemodialysis System manufactured by Fresenius Medical Care North America. | The hemodialysis delivery system which is compatible with the product is Fresenius 2008K manufactured by Fresenius Medical Care North America. | Difference 1 |
| Feature | Pre-Pump<br>Post-Pump<br>Color Coded component<br>Sterile<br>Non-pyrogenic<br>Single Use<br>Prescription Device | Pre-Pump<br>Post-Pump<br>Color Coded component<br>Sterile<br>Non-pyrogenic<br>Single Use<br>Prescription Device | Same |
| Main Configuration | Arteria Line<br>Venous Line | Arteria Line<br>Venous Line | Difference 2 |
| | Air capture chamber | Drip Chamber | |
| | Branch Tubings; | Branch Lines; | |
| | Female Luer Lock | Female Luer Lock | |
| | Clamps | Clamps | |
| | Filters | Filters | |
| Accessory | Drain Bag | Drain Bag | Difference 3 |
| | Transducer Protector | Transducer Protector | |
| | Monitor | Pillow | |
| | Tubing in the Arterial line | Heparin Line | |
| | Priming connector in the Arterial and Venous lines | Recirculating Connector | |
| | Priming Piece, Priming Needle, | / | |

| | | | | |
|---|---|---|---|---|
| | Fluid Replacement Tube, Connecting Tube | | | |
| Sterilization | SAL ($10^{-6}$) | | SAL ($10^{-6}$) | Same |
| Labeling | Direction for Use | | Direction for Use | Same |
| | Indications for Use | | Indications for Use | |
| | Description | | Description | |
| | Warnings and Cautions | | Warnings and Cautions | |
| Physical Performance | Length of arterial Line (mm) | HDJ:3500mm | 3500 | Difference 4 |
| | | HDK:3500mm | | |
| | | HDL:3600mm | | |
| | | HDM:3660mm | | |
| | | HDN:3500mm | | |
| | Length of venous Line (mm) | HDJ:3000mm | 3000 | |
| | | HDK:3000mm | | |
| | | HDL:2900mm | | |
| | | HDM:2400mm | | |
| | | HDN:3000mm | | |
| | Priming Volume (mL) | HDJ:143±10% | 163±10% | |
| | | HDK:147±10% | | |
| | | HDL:153±10% | | |
| | | HDM:162 ±10% | | |
| | | HDN:167±10% | | |
| | Positive pressure (mmHg) | 500 | 500 | Same |
| | Negative Pressure (mmHg) | -300 | -500 | Difference 5 |
| | Blood Flow limits(ml/min) | 500 | 500 | Same |
| | Inner diameter of the venous and arterial lines(mm) | 5.6 | 4.48 | Difference 6 |
| Materials | | Various materials | Various materials | Same |
| Biocompatibility | | | | |
| Cytotoxicity | | No cytotoxicity. | Conforms to ISO 10993 Series | Same |
| Skin Sensitization | | No skin | | |

| | | | | |
|---|---|---|---|---|
| | | sensitization. | | |
| Intracutaneous Reactivity Test | | No intracutaneous reactivity. | | |
| Acute Systemic Toxicity Test | | No systemic toxicity. | | |
| Sub chronic Toxicity Study | | No chronic toxicity. | | |
| Hemolysis Study | | No hemolysis. | | |
| Complement Activation | | No complement activation. | | |
| Prothrombin Time | | The test article compared with that of negative control article is not significant statistically different. | | |
| Partial Thromboplastin Time Study | | The test article compared with that of negative control article is not significant statistically different. | | |
| Genotoxicity | Bacterial Reverse Mutation | No genotoxicity. | | |
| | In Vitro Mammalian Chromosome Aberration Test | No genotoxicity. | | |
| Pyrogenicity | | No potential febrile reaction. | | |

Difference 1 – Compatible Hemodialysis Delivery System

The proposed device and predicate device have the different Compatible Hemodialysis Delivery System. Considering 1) Fresenius 2008K Home Hemodialysis System and Fresenius 2008K are both manufactured by Fresenius Medical Care North America. There is no huge difference. 2) They are both used by the physician in a clinical facility. 3) Stimulated Operation Testing Report demonstrated that the proposed device had good compatibility performance in hemodialysis treatment conditions with

Fresenius 2008K Home Hemodialysis System. Therefore, this difference will not raise new problem on the safety and effectiveness.

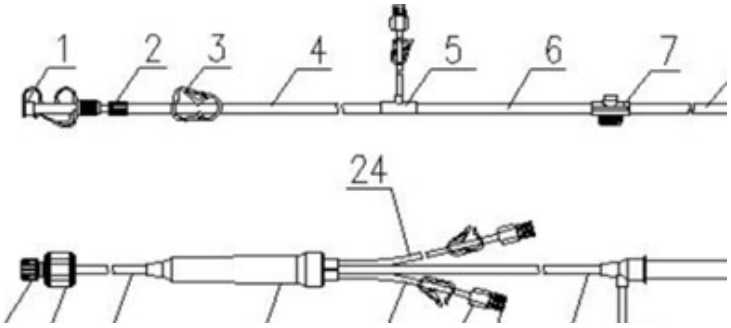
Difference 2 – Main Configuration

The air capture chamber and branch tubing of proposed device is same with the drip chamber and branch lines of predicate device. They are only difference in the name of components. Names of components will not affect the clinical using of the proposed device, therefore, this difference will not raise new problem on the safety and effectiveness.

Difference 3 – Accessory

The predicate device has the accessory of Heparin Line, while the proposed device doesn't have this accessory. However, the component (15 tubing) has been included in the Arterial line of the proposed device. The Heparin Line of predicate device and component (15 tubing) of proposed device are both the path for heparin injection. Therefore, this difference will not raise new problem on the safety and effectiveness.

Fig.1 Assembly Drawing of SANSIN Tubing Sets for Hemodialysis (Arterial line)




The proposed device and predicate device have the same main configuration. The predicate device has the accessory of recirculating connector, while the proposed device doesn't have this accessory. However, the component (Priming connector) has been included in the Arterial and Venous lines of the proposed device. The Recirculating Connector of predicate device and component (Priming connector) of proposed device are both for reducing the amount of normal saline for priming. Therefore, this difference will not raise new problem on the safety and effectiveness.

The proposed device has Priming Piece, Priming Needle, Fluid Replacement Tube and Connecting Tube, while the predicate device doesn't have these accessories. The clinicians will choose these accessories based on the clinical conditions. Having these accessories will not affect the Indications for Use of the proposed device, therefore, this difference will not raise new problem on the safety and effectiveness.

Difference 4- Physical performance (Length of arterial line & venous Line, Priming Volume)

The length of arterial and venous tubes of proposed device is different to that of the predicate device. The difference on the length of arterial and venous tubes leads to the difference on the priming volume. Differences in the tubing length and priming volume can impact the mechanical and performance characteristics of device. The bench tests such as stimulated operation test, pressure leak test, priming volume test, tubing compliance test, mechanical hemolysis test, Tensile Strength Test, Repeated Closing Test and Endurance Pump 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, priming volume will not lead to new safety and effectiveness problems.

Difference 5- Physical performance (Negative Pressure)

The negative pressure limitation of the proposed device is smaller than that of the predicate device. The negative pressure has been tested in the Endurance Pump Test and Endurance Pump Test after Aging. The test result approved that the product can maintain the safety and effectiveness of the product under -300 pressure. The negative pressure will affect the blood flow. The stimulated operation test was conducted to approve that the proposed device meets the requirements of blood flow.
In additional, this negative pressure is included in the user manual. The user will set the negative pressure based on the user manual and will therefore be limited to hemodialysis with a negative pressure up to -300 mmHg as opposed to -500 mmHg for the predicate. Therefore, the difference in negative pressure will not lead to new safety and effectiveness problems.

Difference 6- Physical performance (Inner diameter of the venous and arterial lines)

The inner diameter of the venous and arterial lines for the predicate device is 4.48 mm. The inner diameter of the venous and arterial lines for the proposed device is 5.6 mm. The inner diameter of the venous and arterial lines will affect the blood flow. The stimulated operation test was conducted to approve that the proposed device meets the requirements of blood flow. Therefore, the differences in the inner diameter of the venous and arterial lines will not lead to new safety and effectiveness problems.

7. Non-Clinical Test Conclusion

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 guidances used, see below. The tests performed on the relevant device configurations include:

Repeated closing test
The repeated closing test was performed on proposed device. The test result demonstrated that the

proposed device is able to meet the maximum closing time. This test is an internal test.

Tensile Strength Test

The tensile strength test was performed on proposed device. The test result demonstrated that any connections between the components of the transfusion set of the proposed device, excluding protective caps, shall withstand a static tensile force. 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.

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 test results demonstrated that the proposed device complies with the following standards and guidance. The following tests were conducted as applicable to the subject devices:

- 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 10993-10:2010 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 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP 42-NF 37:2019 <85> Bacterial Endotoxins Test
- USP 42-NF 37:2019 <151> Pyrogen Test (USP Rabbit Test)
- ISO 594-2:1998 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2 Lock fittings
- ISO 8638:2010 Cadiovascular implants and extracorporeal blood circuit for hemodialyzers, hemodialfilters, and hemofilters

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.