April 8, 2022

Bain Medical Equipment (Guangzhou)Co., Ltd.
Zoe Zeng
Regulatory Supervisor
No.10, Juncheng Road, Eastern Area, Economic and
Technological Development
Guangzhou, Guangdong 510760
CHINA

Re: K213015
Trade/Device Name: DORA Disposable A.V. Fistula Needle Sets
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: FIE
Dated: March 7, 2022
Received: March 14, 2022

Dear Zoe Zeng:

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,

Gema Gonzalez
Acting 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

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)*
K213015

Device Name
DORA Disposable A.V. Fistula Needle Sets

Indications for Use *(Describe)*
The DORA Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield is used for protecting from needlestick injury.

The DORA Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment.

The DORA Disposable A.V. Fistula Needle Sets (Dull Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Scab Remover is used for remove the scab at puncture position.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K213015

1. Date of Preparation: 31/03/2022

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd.
No.10 Juncheng Road, No.10, Juncheng Road, Eastern Area, Economic and Technological Development, 510760, Guangdong, P.R.China

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: DORA Disposable A.V. Fistula Needle Sets
Common Name: AVF Needle
Models: See Tab 5 Cover Letter

Regulatory Information
Classification Name: Blood access device and accessories
Classification: II
Product Code: FIE
Regulation Number: CFR 876.5540
Review Panel: Gastroenterology/Urology

Indications for Use:
The DORA Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield is used for protecting from needlestick injury.

The DORA Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment.

The DORA Disposable A.V. Fistula Needle Sets (Dull Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Scab Remover is used for remove the scab at puncture position.

Device Description

The proposed device, DORA Disposable A.V. Fistula Needle Sets, is a non-implantable blood access device, which mainly consists of flexible tube and sharp needle/dull needle. It is available in three types, 1) Needle sets with safety feature, 2) Needle sets without safety feature and 3）Dull Needle sets. Both the three types of proposed device are provided sterile and are for single use only.

The three types of proposed devices are offered in difference configurations with options that include needle gauge, needle length, wing types (fixed wing or rotatable wing).

The proposed device and its package are designed to be provided in Ebeam sterilization. The package could maintain the sterility of the device for three years.

The Protective Shield for injury prevention requires physical action by the clinician to activate and is designed to cover the cannula after treatment. Correct use of this safety feature will eliminate accidental needlestick injuries.

Conditions of Use

The proposed device is provided sterile and is for single use only. It allows for vein puncture access to an Arterial-Venous Fistula (AVF) and the bloodstream of a patient undergoing Hemodialysis and other treatments requiring an extracorporeal circuit of larger volumes of blood.

It shall be used with a FDA cleared hemodialysis blood tubing sets. This product should be used under medical supervision in a medical environment.

Blood Contact Materials and Contact Information

Components	Material	Type of Contact	Contact Duration	Applicable standard
Cannula	Stainless steel	Circulating Blood	<24 hours	ISO 9626:2016
Hub	PC (Polycarbonate)	Circulating Blood	<24 hours	ISO 10993
Tubing	PVC (Polyvinyl chloride)	Circulating Blood	<24 hours	
Female luer lock	PVC (Polyvinyl chloride)	Blood Path Indirect	<24 hours	
Scab Remover	ABS (Acrylonitrile–butadiene–styrene)	Blood Path Indirect	<24 hours	

5. Identification of Predicate Device

510(k) Number: K163025
Product Name: DORA Disposable A.V. Fistula Needle Sets
Manufacturer: Bain Medical Equipment(Guangzhou)Co., Ltd.

6. 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. The test results demonstrated that the proposed device complies with the following standards:

- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods;
- Implanted Blood Access Devices for Hemodialysis, January 21, 2016, Guidance for Industry and Food and Drug Administration Staff
- ASTM F88/F88M – 15, Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929 – 15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- USP <85> Bacterial Endotoxin Limit;
- ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications;

- ISO 10993-3:2014, Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-4:2017 A1:2006, Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity;
- ISO 10993-6:2016, Biological evaluation of medical devices- Part 6: Tests for local effects after implantation;
- 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;
- ASTM F756-17, Standard Practice for Assessment of Hemolotic Properties of Materials.
- ISO 10555-1:2013, Intravascular catheters – Sterile and single-use cathethers – Part 1: General requirements
- ASTM D4169-16, Standard Practice For Performance Testing Of Shipping Containers And Systems.

The following side-by-side performance testings between the proposed device and predicate device have been conducted, and test results demonstrate that the performance of proposed device is similar as that of the predicate device.

- Side-by-Side Parallel Tubing Kinking Test Report；
- Side-by-Side Parallel Leakage Test Report；
- Side-by-Side Parallel Clamp Stop Test Report；
- Side-by-Side Parallel Flow Rate Test Report；
- Report for Wing Torque and Final Lock；
- Side-by-Side Parallel Recirculation Rates for Both Forward and Reverse Flow Test Report；
- Side-by-Side Parallel Priming Volume Test Report

The following performance testings on the proposed device have been conducted.

- Pull Force Between Needle Protective Cap and Scab Remover
- Sharpness Test of The Scab Remover
- Bending Strength Test When Using Scab Remover
- Shear Fracture Test of Scab Remover
- Mechanical Hemolysis Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Item	Proposed Device K201888 Dora Disposable A.V. Fistula Needle Sets			Predicate Device K163025 Dora Disposable A.V. Fistula Needle Sets	
Product Code	FIE			FIE	
Regulation Number	CFR 876.5540			CFR 876.5540	
Intended Use	The DORA Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield is used for protecting from needlestick injury. The DORA Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. The DORA Disposable A.V. Fistula Needle Sets (Dull Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Scab Remover is used for remove the scab at puncture position.			The DORA Disposable A.V. Fistula Needle Sets (Safety Needle Series) are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment. Protective Shield aids in the prevention of accidental needlesticks. The DORA Disposable A.V. Fistula Needle Sets are single-use sterile medical devices intended to be used as vein puncture for hemodialysis treatment.	
Configuration	Disposable A.V. Fistula Needle Sets (Safety Needle Series)	Disposable A.V. Fistula Needle Sets	Disposable A.V. Fistula Needle Sets (Dull Needle Series)	AVF Needle sets **with** safety feature	AVF Needle sets **without** safety feature
Sterile	*Ebeam Sterilized*			*Gamma Sterilized*	
	SAL:10^{-6}			*SAL:10^{-6}*	
Single Use	Yes			Yes	
Biocompatibility	*Comply with ISO 10993 series standards*			*Comply with ISO 10993 series standards*	
AV Fistula Needle Set Performance Testing	Flow rate testing; Leakage testing; Particulate contamination testing; Tensile strength testing			Flow rate testing; Leakage testing; Particulate contamination testing; Tensile strength testing	
Needle Performance	Complied with ISO/FDIS 9626:2016			Complied with ISO/FDIS 9626:2016	
Product Specification	available in numerous combinations with the following options Gauge: 14G,15G, 16G, 17G			available in numerous combinations with the following options Gauge: 15G, 16G, 17G	
Materials of Use	Stainless steel, PP, PC, PVC, PE, HDPE, ABS			Stainless steel, PP, PC, PVC, PE, HDPE, ABS	
Additive	Silicon Oil			Silicon Oil	

The proposed device has the similar configuration, intended use and safety feature as the

predicated device. The non-clinical testing demonstrates the product performance of proposed device is similar as that of the predicate device or the product performance of proposed device is acceptable. The biocompatibility of the proposed device comply with ISO 10993 series standards.

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 devices.