DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 20, 2017

Bain Medical Equipment (Guangzhou) Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K163025
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: II
Product Code: FIE
Dated: June 8, 2017
Received: June 9, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163025

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 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.

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 SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163025

1. Date of Preparation: 7/13/2017

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: DORA Disposable A.V. Fistula Needle Sets
Common Name: AVF Needle
Models:

AVF needle sets without safety feature	BAIN-A.V.F-001G, BAIN-A.V.F-002G, BAIN-A.V.F-003G, BAIN-A.V.F-004G, BAIN-A.V.F-005G, BAIN-A.V.F-006G, BAIN-A.V.F-007G, BAIN-A.V.F-008G, BAIN-A.V.F-009G, BAIN-A.V.F-010G, BAIN-A.V.F-011G, BAIN-A.V.F-012G.
AVF needle sets with safety feature	BAIN-A.V.F-001SG, BAIN-A.V.F-002SG, BAIN-A.V.F-003SG, BAIN-A.V.F-004SG, BAIN-A.V.F-005SG, BAIN-A.V.F-006SG, BAIN-A.V.F-007SG, BAIN-A.V.F-008SG, BAIN-A.V.F-009SG, BAIN-A.V.F-010SG, BAIN-A.V.F-011SG, BAIN-A.V.F-012SG.

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 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.

Device Description

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

The two 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 Gamma 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.

The proposed device is used in conjunction with following hemodialysis blood tubing sets during clincial use.

K Number	Product Name	Manufacturer
K161582	DORA Tubing Sets for Hemodialysis	Bain Medical Equipment (Guangzhou) Co. Ltd
K952631	Braun Hemodialysis Blood Circuits	B. Braun Medical, Inc.
K934803	Arterial & Venous Blood Tubing Sets for Hemodialysis	Baxter Healthcare Corp.
K013634	Bioteque 3 in 1 Hemodialysis Blood Tubing Pack	Bioteque Corp.
K992930	Bioteque Hemodialysis Blood Tubing Set	Bioteque Corp.
K000451	Fresenius Combillines Single Needle Blood Tubing Set, Catalog #03-2290	Fresenius Medical Care North America
K001107	Fresenius Combilines Low Volume Blood Tubing Set, Models 03-2291 (Post Pump) and 03-2292 (Pre-Pump)	Fresenius Medical Care North America
K012242	Fresenius Arterial Bloodline Sets for Hemodialysis, Fresenius Combi Sets Hemodialysis Blood Tubing Sets	Fresenius Medical Care North America
K801016	Gambro G Series Blood Line Sets for Hem.	Gambro, Inc.
K063290	Gambro Quickset Bloodlines	Gambro Renal Products
K982340	Extracorporeal Blood Circuit	Haidylena Medical Egypt
K032975	JMS Blood Tubing Sets	JMS North America Corp.
K873516	Kawasumi Blood Tubing Line	Kawasumi Laboratories Co., Ltd.
K953823	Arterial Venous Blood Tubing Set	Medisystems Corp.
K001465	Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set	Nipro Medical Corp.
K010264	Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set	Nipro Medical Corp.
K072024	Nipro Blood Tubing Set with Transducer Protector and Priming Set, Model A201-A219, V801-V806, 5M9634, 5M9693	Nipro Medical Corp.
K112628	Nipro Blood Tubing Set with Transducer Protector and Priming Set	Nipro Medical Corporation
K090255	Blood Tubing Sets (Sterile Fluid Path)	Nxstage Medical, Inc.
K014140	Renax Hemodialysis Blood Tubing Set; Sunder Hemodialysis Blood Tubing Set	Sunder Biomedical Tech. Co., Ltd.
K955277	Arterial Blood Tubing Set for Single Needle Hemodialysis	Baxter Healthcare Corp.
K770691	Gambro Venous Blood Line	Gambro, Inc.
K082719	Nikkline Blood Tubing Lines With Transducer Protectors, Models AV06A-P, AVO6B-P, AV06C-P	Nikkiso Co. Ltd.
K972206	Nipro Blood Tubing Set with Transducer and Solution Set for Hemodialysis	Nipro Medical Corp.

5. Identification of Predicate Device

510(k) Number: K071145
Product Name: NIPRO SafeTouch TULIP^{TM} Safety Fistula Needle
Manufacturer: NIPRO Medical Corporation

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/FDIS 9626:2016, Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods;
- 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 594-1:1986, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements;
- ISO 594-2:1998, Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings;
- ISO 10993-3:2014, Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-4:2002 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 10993-6:2007, 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 10993-11:2006, Biological evaluation of medical devices Part 11: Tests for systemic toxicity;
- ASTM F756-13, 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 testing 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.

- Simulated Use Needlestick Prevention Testing;
- Needle Performance Testing;
- Female Conical Fitting Testing;
- Mechanical Testing, including wing torque test, final lock test, needle pushback test and mechanical hemolysis test;
- Tensile Strength Testing, including tube to wing pull test, tube to joint test, needle to cover pull test and cannula to hub test;
- Tubing Kinking Test;
- Leakage Testing, including liquid leakage test and air leakage test;
- Clamp Stop Testing;
- Flow Rate Testing;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K071145
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 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.		The NIPRO SafeTouch TULIP™ Safety Fistula Needle is intended for use as a blood access device for blood purification and for other treatments requiring an extracorporeal circuit of larger volumes of blood. Secondly, it is designed with an anti-stick needle protector requiring physical action by the clinican to aid in the prevention of accidental needlesticks. The compatibility of available configurations is the responsibility of the physician in charge.
Configuration	AVF Needle sets **with** safety feature	AVF Needle sets **without** safety feature	1) Protective Cap, 2) Cannula, 3) Rotatable Hub, 4) Fixed / Rotatable Wing, 5) Tubing, 6) On-off Clamp, 7) Female Luer Lock 8) Cap for FLL. 9) Protective Shield
	1) Protective Cap, 2) Cannula, 3) Rotatable Hub, 4) Fixed / Rotatable Wing, 5) Tubing, 6) On-off Clamp, 7) Female Luer Lock 8) Cap for FLL. 9) Protective Shield	1) Protective Cap, 2) Cannula, 3) Rotatable Hub, 4) Fixe / Rotatable Wing, 5) Tubing, 6) On-off Clamp, 7) Female Luer Lock 8) Cap for FLL.	
Sterile	*Gamma Sterilized*		*EO/Gamma Sterilized*
	SAL:10^{-6}		*SAL:10^{-6}*
Single Use	Yes		Yes
Biocompatibility	*Comply with ISO 10993 series standards;* Cytotoxicity; Sensitization Irritation sensitivity Systemic toxiicity Pyrogen Hymodialysis		*Comply with ISO 10993 series standards.*

Item	Proposed Device		Predicate Device K071145	
	Thromboresistance Partial thromboplastin time Complement activation Bacterial reverse mutation Mammalian chromosome aberration Mouse bone marrow micronucleus Activated clotting time of whole blood Platelet adhesion Muscle implantation Subchronic systemic toxicity			
AV Fistula Needle Set Performance Testing	Flow rate testing; Leakage testing; Particulate contamination testing; Tensile strength testing		Unknown	
Needle Performance	Complied with ISO/FDIS 9626:2016		Complied with ISO 9626:1991, AMENDMENT 1 2001	
Product Specification	available in numerous combinations with the following options		available in numerous combinations with the following options	
	Gauge	15G, 16G, 17G	Gauge	14G, 15G, 16G, 17G
	Cannula length	25 *mm*, 32 *mm*	Cannula length	25 *mm*, 32 *mm*
			Tube length	150 *mm*, 300 *mm*
Safety Feature	1, Color: White locking Protective Shield; 2, Shape: two tubular walls 3, Method: slide the protective shield forward until the wings are locked in the slot of the two tubular walls.		1, Color: Transparent locking safety shield; 2, Shape: four tubular wall (petals) 3, Method: slide the protective shield forward until the wings are locked in the slot of the 2 petals.	

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.