DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 16, 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: K161582
Trade/Device Name: DORA Tubing Sets for Hemodialysis
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FJK
Dated: May 11, 2017
Received: May 19, 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 yours,

Benjamin R. Fisher -S

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)*
K161582

Device Name
DORA Tubing Sets for Hemodialysis

Indications for Use *(Describe)*
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.

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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Tab #5 510(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: K161582

1. Date of Preparation: 03/14/2017

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd
No.10 Juncheng Road, Eastern Zone of Guangzhou Economic & Technological Development District, 510760, Guangdong, P.R.China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: DORA Tubing Sets for Hemodialysis
Common Name: Blood tubing sets
Model(s): BAIN-BL-001E, BAIN-BL-002E, BAIN-BL-003E, BAIN-BL-004E, BAIN-BL-005E

Regulatory Information

Classification Name: Set, Tubing, Blood, With And Without Anti-Regurgitation Valve
Classification: 2
Product Code: FJK
Regulation Number: 876.5820
Review Panel: Gastroenterology/Urology

Intended Use Statement:
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.

Device Description

The proposed devices, DORA Tubing Sets for Hemodialysis, 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 two accessories which are recirculate connector and drainage bag.

They are available in five (5) models, following very similar design principles, and has some differences in dimensions and configurations.

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

5. Identification of Predicate Device(s)

K072024
Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set
Nipro Medical Coporation

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 8638 Third Edition 2010-07-01, Cadiovascular Implants And Extracorporeal Blood

Circuit For Hemodialyzers, Hemodialfilters, And Hemofilters. 9-89

- ISO 594-2 Second Edition 1998-09-01, Conical Fittings With A 6% (Luer) Taper For Syringes, Needles And Certain Other Medical Equipment - Part 2: Lock Fittings. 6-129
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-4:2002 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood;
- ASTM F 756-08, Standard practice for assessment of hemolytic properties of material;
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials

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, K072024
Device Class	II	II
Product Code	FJK	FJK
Regulation Number	21 CFR part 876.5820	21 CFR part 876.5820
Intended Use	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.	Nipro® Set – Blood Tubing Set with Transducer Protector and Priming Set are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis.
	The compatibility of available configurations is the responsibility of the physician/clinician in charge.	The compatibility of available configuration is the responsibility of the physician in charge.
Feature	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device	Pre-Pump Post-Pump Color Coded component Sterile Non-pyrogenic Single Use Prescription Device
Configuration	Arteria Line Venous Line	Tubing

	Drip Chamber	Drip Chamber
	Branch Lines	Infusion Tubing; Pressure Monitoring Lines;
	Female Luer Lock	Ports
	Clamps	Clamps
	Filter	Filters
	Drain Bag Recirculating Connector	N.A.
Performance	Conforms to ISO 8638:2010 ISO 594-2: 1998	Conforms to ISO 8638:2010 ISO 594-2: 1998
Materials	Various materials	Unknown
Biocompatibility	Cytotoxicity; Sensitization Intracutaneous reactivity; Acute systemic toxicity; Hemolysis Partial Thromboplastin Time Complement System In vitro Chromosomal Aberration Bacterial Reverse Mutation Mouse Bone Marrow Micronucleus Pyrogen	Conforms to ISO 10993-1
Sterilization	SAL (10^{-6})	SAL (10^{-6})

Discussion: The intended use of the proposed and predicate device is different in text. The proposed device has two (2) additional accessories which are drain bag and the recirculating. These two (2) accessories will not affect the actual hemodialysis; the materials of the propose device have been evaluated for their biocompatibility. Therefore, no difference will result in any safety and effectiveness issue.

Conclusion

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