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
Indications for Use

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
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.**
   No.10 Juncheng Road, Eastern Zone of Guangzhou Economic&Technological Development District, 510760, Guangdong, P.R.China

   Establishment Registration Number: Not yet registered

   Contact Person: Sophia Shao
   Position: Assistant Manager
   Tel: +86-20-66856868
   Fax: +86-20-32067500
   Email: sophia@baingz.com

3. **Designated Submission Correspondent**

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

   **Mid-Link Consulting Co., Ltd**
   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net
4. Identification of Proposed Device

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


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 the following hemodialysis blood tubing sets during clinical use.

<table>
<thead>
<tr>
<th>K Number</th>
<th>Product Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>K161582</td>
<td>DORA Tubing Sets for Hemodialysis</td>
<td>Bain Medical Equipment (Guangzhou) Co. Ltd</td>
</tr>
<tr>
<td>K952631</td>
<td>Braun Hemodialysis Blood Circuits</td>
<td>B. Braun Medical, Inc.</td>
</tr>
<tr>
<td>K934803</td>
<td>Arterial &amp; Venous Blood Tubing Sets for Hemodialysis</td>
<td>Baxter Healthcare Corp.</td>
</tr>
<tr>
<td>K013634</td>
<td>Bioteque 3 in 1 Hemodialysis Blood Tubing Pack</td>
<td>Bioteque Corp.</td>
</tr>
<tr>
<td>K992930</td>
<td>Bioteque Hemodialysis Blood Tubing Set</td>
<td>Bioteque Corp.</td>
</tr>
<tr>
<td>K000451</td>
<td>Fresenius Combilines Single Needle Blood Tubing Set, Catalog #03-2290</td>
<td>Fresenius Medical Care North America</td>
</tr>
<tr>
<td>K001107</td>
<td>Fresenius Combilines Low Volume Blood Tubing Set, Models 03-2291 (Post Pump) and 03-2292 (Pre-Pump)</td>
<td>Fresenius Medical Care North America</td>
</tr>
<tr>
<td>K012242</td>
<td>Fresenius Arterial Bloodline Sets for Hemodialysis, Fresenius Combi Sets Hemodialysis Blood Tubing Sets</td>
<td>Fresenius Medical Care North America</td>
</tr>
<tr>
<td>K063290</td>
<td>Gambio Quicksel Bloodlines</td>
<td>Gambio Renal Products</td>
</tr>
<tr>
<td>K982340</td>
<td>Extracorporeal Blood Circuit</td>
<td>Haidylena Medical Egypt</td>
</tr>
<tr>
<td>K032975</td>
<td>JMS Blood Tubing Sets</td>
<td>JMS North America Corp.</td>
</tr>
<tr>
<td>K873516</td>
<td>Kawasaki Blood Tubing Line</td>
<td>Kawasaki Laboratories Co., Ltd.</td>
</tr>
<tr>
<td>K953823</td>
<td>Arterial Venous Blood Tubing Set</td>
<td>MediSystems Corp.</td>
</tr>
<tr>
<td>K001465</td>
<td>Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set</td>
<td>Nipro Medical Corp.</td>
</tr>
<tr>
<td>K010264</td>
<td>Nipro Blood Tubing Set for Hemodialysis with Transducer Protectors and Priming Set</td>
<td>Nipro Medical Corp.</td>
</tr>
<tr>
<td>K072024</td>
<td>Nipro Blood Tubing Set with Transducer Protector and Priming Set, Model A201-A219, V801-V806, 5M9634, 5M9693</td>
<td>Nipro Medical Corp.</td>
</tr>
<tr>
<td>K112628</td>
<td>Nipro Blood Tubing Set with Transducer Protector and Priming Set</td>
<td>Nipro Medical Corporation</td>
</tr>
<tr>
<td>K090255</td>
<td>Blood Tubing Sets (Sterile Fluid Path)</td>
<td>Nxstage Medical, Inc.</td>
</tr>
<tr>
<td>K770691</td>
<td>Gambro Venous Blood Line</td>
<td>Gambro, Inc.</td>
</tr>
<tr>
<td>K082719</td>
<td>Nikkline Blood Tubing Lines Transducer Protectors, Models AV06A-P; AV06B-P; AV06C-P</td>
<td>Nikkiso Co. Ltd.</td>
</tr>
<tr>
<td>K972206</td>
<td>Nipro Blood Tubing Set with Transducer and Solution Set for Hemodialysis</td>
<td>Nipro Medical Corp.</td>
</tr>
</tbody>
</table>

5. Identification of Predicate Device

510(k) Number: K071145

Product Name: NIPRO SafeTouch TULIP™ 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;
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 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;
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>
<thead>
<tr>
<th>Item</th>
<th>Proposed Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Code</strong></td>
<td>FIE</td>
<td>FIE</td>
</tr>
<tr>
<td><strong>Regulation Number</strong></td>
<td>CFR 876.5540</td>
<td>CFR 876.5540</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>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.</td>
<td>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 clinician to aid in the prevention of accidental needlesticks. The compatibility of available configurations is the responsibility of the physician in charge.</td>
</tr>
<tr>
<td><strong>Configuration</strong></td>
<td>AVF Needle sets with safety feature</td>
<td>AVF Needle sets without safety feature</td>
</tr>
<tr>
<td><strong>Sterile</strong></td>
<td>Gamma Sterilized</td>
<td>EO/Gamma Sterilized</td>
</tr>
<tr>
<td></td>
<td>SAL:10⁻⁶</td>
<td>SAL:10⁻⁶</td>
</tr>
<tr>
<td><strong>Single Use</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Comply with ISO 10993 series standards</td>
<td>Comply with ISO 10993 series standards</td>
</tr>
<tr>
<td></td>
<td>Cytotoxicity; Sensitization; Irritation sensitivity; Systemic toxicity; Pyrogen; Hemodialysis</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Proposed Device</td>
<td>Predicate Device</td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
<td>Thromboresistance</td>
<td>K071145</td>
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<tr>
<td></td>
<td>Partial thromboplastin time</td>
<td></td>
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<tr>
<td></td>
<td>Complement activation</td>
<td></td>
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<tr>
<td></td>
<td>Bacterial reverse mutation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mammalian chromosome aberration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mouse bone marrow micronucleus</td>
<td></td>
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<tr>
<td></td>
<td>Activated clotting time of whole blood</td>
<td></td>
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<tr>
<td></td>
<td>Platelet adhesion</td>
<td></td>
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<tr>
<td></td>
<td>Muscle implantation</td>
<td></td>
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<tr>
<td></td>
<td>Subchronic systemic toxicity</td>
<td></td>
</tr>
<tr>
<td>AV Fistula Needle Set Performance Testing</td>
<td>Flow rate testing; Leakage testing; Particulate contamination testing; Tensile strength testing</td>
<td>Unknown</td>
</tr>
<tr>
<td>Product Specification</td>
<td>available in numerous combinations with the following options</td>
<td>available in numerous combinations with the following options</td>
</tr>
<tr>
<td>Cannula length</td>
<td>25 mm, 32 mm</td>
<td>25 mm, 32 mm</td>
</tr>
<tr>
<td>Tube length</td>
<td></td>
<td>150 mm, 300 mm</td>
</tr>
<tr>
<td>Safety Feature</td>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.