March 8, 2017

Beijing Fert Technology Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K161898
   Trade/Device Name: Burette-type Infusion Sets for Single Use, Disposable Infusion Sets with Precision Filters, Disposable Infusion Set
   Regulation Number: 21 CFR 880.5440
   Regulation Name: Intravascular Administration Set
   Regulatory Class: Class II
   Product Code: FPA
   Dated: February 28, 2017
   Received: March 3, 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The devices are indicated for the delivery of fluids from a container to a patient’s vascular system.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“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 Title 21, CFR Section 807.92.

The assigned 510(k) Number: K161898

1. Date of Preparation: 03/07/2017

2. Sponsor Identification

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No. 9, Zhangguozhuang Village, Changxindian Town, Feng Tai District, Beijing, 100072, China

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Position: Quality Director
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Fax: +86-10-83805808
Email: zhangmeng@pwmedtech.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (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: Burette-type Infusion Sets for Single Use
   Disposable Infusion Sets with Precision Filters
   Disposable Infusion Set
Common Name: Disposable Infusion Set

Regulatory Information

Classification Name: Set, Administration, Intravascular

Classification: Class II
Product Code: FPA
Regulation Number: 21CFR 880.5440
Review Panel: General Hospital;

Indications for Use:

The devices are indicated for the delivery of fluids from a container to a patient’s vascular system.

Device Description:

The proposed devices are indicated for the delivery of fluids from a container to a patient’s vascular system through the infusion needle under the action of gravity. The proposed devices are comprised of air filter, protective cap of closure-piercing device, closure-piercing device, drip chamber, flexible tubing, flow regulator, filter and an infusion needle attached to a luer adaptor. For the Burette-type Infusion Sets for Single Use, an additional component of burette can used for quantitative infusion. For Disposable Infusion Sets with Precision Filters, a precision membrane is provided for filtration operation.

5. Identification of Predicate Device

510(k) Number: K112204
Product Name: KDL Disposable Infusion Set

6. Identification of Reference Device

510(k) Number: K972839
Product Name: PROTOS® 100ml Burette Infusion Set/PROTOS® 150ml Burette Infusion

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

- ISO 8536-4:2010 AMD 1 2013 Infusion equipment for medical use, Part 4: Infusion sets for single use, gravity feed
- ISO 8536-5:2004 Infusion equipment for medical use- Part 5: Burette infusion sets for single use, gravity feed
- 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 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings
- ISO 9626:1991 AMD 1 2001 Stainless steel needle tubing for the manufacture of medical devices;
- ISO 7864: 1993 Sterile hypodermic needles for single use
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F 88/88M-09 Standard test method for seal strength of flexible barrier materials;
- ASTM F1140/1140M-13 Standard test methods for internal pressurization failure resistance of unrestrained packages
- USP38-NF33 <85> Bacterial Endotoxins Tests.
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ASTM F 756-13 Standard practice for assessment of hemolytic properties of materials

8. Clinical Test Conclusion

No clinical study is included in this submission.
9. Substantially Equivalent (SE) Comparison

<table>
<thead>
<tr>
<th>Table 1 Comparison of Technology Characteristics</th>
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<td><strong>Product Code</strong></td>
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<td><strong>Regulation Number</strong></td>
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<td><strong>Indications for Use</strong></td>
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### 510(k) Summary

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<tr>
<th></th>
<th>Infusion Needle</th>
<th>Check valve</th>
<th>Infusion Needle</th>
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<tbody>
<tr>
<td></td>
<td>Protective Cap of Infusion Needle</td>
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<td>Protective Cap of Infusion Needle</td>
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#### Biocompatibility

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<th>Intracutaneous Reactivity</th>
<th>Skin Sensitization</th>
<th>Acute Systemic Toxicity</th>
<th>Hemolysis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No Cytotoxicity</td>
<td>No intracutaneous Reactivity</td>
<td>No Sensitization</td>
<td>No Systemic Toxicity</td>
<td>No Hemolysis</td>
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</tbody>
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- Differences between the subject device and predicate device indication for use are not identical word for word. However, the minor differences do not raise new questions of safety and effectiveness of the device. The reference device K972839 PROTOS® Burette Infusion Set was leveraged for the burette component of the subject device.

10. Substantially Equivalent (SE) Conclusion

Based upon the indications for use, technological characteristics, and the results of the performance testing, the subject devices have been demonstrated to be substantially equivalent to the predicate.