May 31, 2017

SHINVA ANDE Healthcare Apparatus Co., Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai 200120
CHINA

Re: K162601
   Trade/Device Name: Infusion Set for Single Use
   Regulation Number: 21 CFR 880.5440
   Regulation Name: Intravascular Administration Set
   Regulatory Class: Class II
   Product Code: FPA
   Dated: April 26, 2017
   Received: April 28, 2017

Dear Ms. 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" (21CFR 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
## Change Control Table, Change History

<table>
<thead>
<tr>
<th>Version</th>
<th>Document Author</th>
<th>Document Approver</th>
<th>Date Approved</th>
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<td>1.00</td>
<td>Name, Title, Office</td>
<td>Name, Title, Office</td>
<td>MM/DD/YYYY</td>
</tr>
</tbody>
</table>

Complete Change Control Table (all versions) retained in SWIFT Docs.
Indications for Use

510(k) Number (if known)
K162601

Device Name
Infusion Set for Single Use

Indications for Use (Describe)
The device is 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.

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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 Title 21, CFR Section 807.92.

The assigned 510(k) Number: K162601

1. Date of Preparation: 05/25/2017

2. Sponsor Identification

**SHINVA ANDE Healthcare Apparatus Co., Ltd.**
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)  
Ms. Ying Xu (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**  
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Tel: +86-21-22815850,  
Fax: 240-238-7587  
Email: info@mid-link.net

4. Identification of Proposed Device

**Trade Name:** Infusion Set for Single Use

**Regulatory Information**

Regulation Name: Intravascular administration set  
Classification: II  
Product Code: FPA  
Regulation Number: 21CFR 880.5440  
Review Panel: General Hospital
Indications for Use:
The device is indicated for the delivery of fluids from a container to a patient’s vascular system.

Device Description
The proposed devices are indicated for the gravity infusion of fluids from a container to a patient’s vascular system through an IV catheter or infusion needle. There are ten different models, each a different configuration comprised of various components which may include: protective cap, spike, air filter, drip chamber, precision filter, flexible tube, check valve, injection site, roller clamp, flow regulator, pinch clamp and luer lock connector. The devices are provided sterile and are single use.

5. Identification of Predicate Device

510(k) Number: K121803
Product Name: Intravascular Administration Set
510k Holder: Acta Medical

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to determine that the proposed device met all design specifications to claim Substantially Equivalence (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 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 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals;
- ASTM F 88/F88M-09 Standard test method for seal strength of flexible barrier materials;
- USP38-NF33 <85> Bacterial Endotoxins Test.
- 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
- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- USP 38-NF 33<151> Pyrogen Test
- Microbial Ingress Testing (Needleless Valve-Y Injection Site)
- ASTM F838-15-Standard Test for Determining Bacterial Retention of Membrane Filter (0.2 Micron Filter test)
- Flow Regulator Performance (Internal Specification)
- 1.2 Micron Filter Test (Internal Specification)

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>Product Code</td>
<td>FPA</td>
<td>Same K121803</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>21 CFR 880.5440</td>
<td>Same</td>
</tr>
<tr>
<td>Indication for Use</td>
<td>The device is indicated for the delivery of fluids from a container to a patient’s vascular system.</td>
<td>Acta Medical Intravascular administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. Acta Medical infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.</td>
</tr>
<tr>
<td>Configuration</td>
<td>Protector Cap of Spike Spike Air Vent Air Filter Drip Chamber Fluid Filter Flexible Tube Check Valve Needle Free Y Injection Site Roller Clamp Y Injection Site Precision Filter Pinch Clamp Luer Lock Connector Protector Cap of Luer Lock Connector</td>
<td>Similar, except for the additional model Minibore extension set</td>
</tr>
<tr>
<td>Sterile</td>
<td>EO sterilized</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>SAL 10^{-6}</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Single Use</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td></td>
<td></td>
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<tr>
<td>--------------------------</td>
<td></td>
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<tr>
<td>Cytotoxicity</td>
<td></td>
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<tr>
<td>Intracutaneous Reactivity</td>
<td></td>
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<tr>
<td>Skin Sensitization</td>
<td>Conform with ISO 10993 requirements</td>
<td></td>
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<tr>
<td>Acute Systemic Toxicity</td>
<td></td>
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<tr>
<td>Hemolysis Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrogen Test</td>
<td>Conform with ISO 10993 requirements</td>
<td></td>
</tr>
</tbody>
</table>

Device Comparison: The predicate device and subject device are similar in model configurations except the predicate device has an additional model, an extension set. The indications for use for the subject device and predicate device are similar except the predicate device has additional language to include the extension set and some models will come with or without a flow control feature. These minor differences in device design and indications for use do not raise different questions of safety or effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the non-clinical performance testing, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.