DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2017

Jiangxi Hongda Medical Equipment Group, Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K163160
Trade/Device Name: Sterile Single-use Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 10, 2017
Received: March 21, 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 -S

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

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)*

K163160

Device Name
Sterile Single-use Infusion Set

Indications for Use *(Describe)*
The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

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."*

# Exhibit #2 510(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: K163160

1. Date of Preparation: 04/17/2017

2. Sponsor Identification

**JiangXi HongDa Medical Equipment Group Ltd.**
No. 39 South Shengli Road, Jinxian County, Nanchang City,
Jiangxi Province, 331700, China

Establishment Registration Number: Not yet registered.

Contact Person: Xiaohua Yang
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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**
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: Sterile Single-use Infusion Set
Common Name: Disposable Infusion Set

Regulatory Information

Classification Name: Set, Administration, Intravascular;
Classification: II;
Product Code: FPA;
Regulation Number: 21CFR 880.5440
Review Panel: General Hospital;

Indication for Use:
The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Device Description

The proposed device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein under the action of gravity. The proposed device is provided with/without injection needle. It is comprised of protective cap of spike, spike, air vent, air filter, drip chamber, fluid filter, flexible tube, injection site, roller clamp, luer lock connector, protector cap of luer lock connector. The devices are provided sterile and single use.

5. Identification of Predicate Device

Premark Notification
510(k) Number: K112204
Trade Name: KDL Disposable Infusion Set
Classification Name: Set, Administration, Intravascular
Manufacturer: Shanghai Kindly Enterprise Development Group Co., Ltd

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 provided in this submission include:

Physical, Mechanical and Chemical Tests performed on the proposed device

| | |
|---|---|
| Particulate contamination | Clause 6.1 of ISO 8536-4:2010 AMD1 2013 |
| Leakage | Clause 6.2 of ISO 8536-4:2010 AMD1 2013 |
| Tensile strength | Clause 6.3 of ISO 8536-4:2010 AMD1 2013 |
| Closure-piercing device | Clause 6.4 of ISO 8536-4:2010 AMD1 2013 |
| Air-inlet device | Clause 6.5 of ISO 8536-4:2010 AMD1 2013 |
| Tubing | Clause 6.6 of ISO 8536-4:2010 AMD1 2013 |
| Fluid filter | Clause 6.7 of ISO 8536-4:2010 AMD1 2013 |
| Drip chamber and drip tube | Clause 6.8 of ISO 8536-4:2010 AMD1 2013 |
| Flow regulator | Clause 6.9 of ISO 8536-4:2010 AMD1 2013 |
| Flow rate of infusion fluid | Clause 6.10 of ISO 8536-4:2010 AMD1 2013 |
| Injection site | Clause 6.11 of ISO 8536-4:2010 AMD1 2013 |
| Male conical fitting | Clause 6.12 of ISO 8536-4:2010 AMD1 2013 |
| Protective caps | Clause 6.13 of ISO 8536-4:2010 AMD1 2013 |
| Reducing (oxidizable) matter | Clause 7.1 of ISO 8536-4:2010 AMD1 2013 |
| Metal ions | Clause 7.2 of ISO 8536-4:2010 AMD1 2013 |
| Titration acidity or alkalinity | Clause 7.3 of ISO 8536-4:2010 AMD1 2013 |
| Residue on evaporation | Clause 7.4 of ISO 8536-4:2010 AMD1 2013 |
| UV absorption of extract solution | Clause 7.5 of ISO 8536-4:2010 AMD1 2013 |

| | |
|---|---|
| Materials | Clause 5 of ISO 8536-14:2016 |
| Tubing specifications | Clause 6.1 of ISO 8536-14:2016 |
| Operating temperature | Clause 6.2 of ISO 8536-14:2016 |
| Construction | Clause 6.3 of ISO 8536-14:2016 |
| Flow rate | Clause 6.4 of ISO 8536-14:2016 |

| | |
|---|---|
| Materials | Clause 3 of ISO 9626:1991/AMD-1:2001 |
| Surface finish | Clause 4 of ISO 9626:1991/AMD-1:2001 |
| Cleanliness | Clause 5 of ISO 9626:1991/AMD-1:2001 |
| Limits for acidity and alkalinity | Clause 6 of ISO 9626:1991/AMD-1:2001 |
| Size designation | Clause 7 of ISO 9626:1991/AMD-1:2001 |
| Dimensions | Clause 8 of ISO 9626:1991/AMD-1:2001 |
| Stiffness | Clause 9 of ISO 9626:1991/AMD-1:2001 |
| Resistance to breakage | Clause 10 of ISO 9626:1991/AMD-1:2001 |
| Resistance to corrosion | Clause 11 of ISO 9626:1991/AMD-1:2001 |

| | |
|---|---|
| Cleanliness | Clause 4 of ISO 7864:1993 |
| Limits for acidity or alkalinity | Clause 5 of ISO 7864:1993 |
| Limits for extractable metals | Clause 6 of ISO 7864:1993 |

| | |
|---|---|
| Size designation | Clause 7 of ISO 7864:1993 |
| Colour coding | Clause 8 of ISO 7864:1993 |
| Needle hub | Clause 9 of ISO 7864:1993 |
| Sheath | Clause 10 of ISO 7864:1993 |
| Needle tube | Clause 11 of ISO 7864:1993 |
| Needle point | Clause 12 of ISO 7864:1993 |
| Performance | Clause 13 of ISO 7864:1993 |

| | |
|---|---|
| Gauge | Clause 4.1 of ISO 594-1:1986 |
| Liquid leakage | Clause 4.2.1 of ISO 594-2:1998 |
| Air leakage | Clause 4.2.2 of ISO 594-2:1998 |
| Separation force | Clause 4.3 of ISO 594-2:1998 |
| Unscrewing torque | Clause 4.4 of ISO 594-2:1998 |
| Ease of assembly | Clause 4.5 of ISO 594-2:1998 |
| Resistance to overriding | Clause 4.6 of ISO 594-2:1998 |
| Stress cracking | Clause 4.7 of ISO 594-2:1998 |

Sterile Barrier Packaging Testing performed on the proposed device:

| | |
|---|---|
| Seal strength | ASTM F88/F88-09 |
| Internal pressure | ASTM F1140/F1140M-13 |
| Dye Penetration | ASTM F 1929-12 |

Sterilization and Shelf Life Testing performed on the proposed device:

| | |
|---|---|
| EO residue | ISO 10993-7:2008 |
| ECH residue | ISO 10993-7:2008 |
| Bacteria Endotoxin Limit | USP 36-NF 31 <85> |
| Shelf Life Evaluation | Physical, Mechanical, Chemical, Package and Sterility Tests were performed on accelerated aging samples to verify the claimed shelf life of the device |

Biocompatibility Testing:

The patient-contact materials of blood collection sets are identified and biocompatibility testing is performed according to ISO 10993 standards.

Transportation Testing

Transportation test is performed on the final product to verify its package integrity during transportation.

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 K112204 | |
|---|---|---|---|---|
| Product Code | FPA | | Same | |
| Regulation Number | 21 CFR 880.5440 | | Same | |
| Indication for Use | The device is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. | | KDL Disposable Infusion Set is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein. | |
| Configuration and material | Configuration | Material | Configuration | Material |
| | Protector Cap of Spike | HDPE | Protective Cap of Closure-piercing Device | Unknown |
| | Spike | ABS | Closure-piercing Device | |
| | Air Vent | PVC | Air Filter | |
| | Drip Chamber | PVC | Drip Chamber | |
| | Fluid Filter | ABS | Fluid Filter | |
| | Flexible Tube | PVC | Flexible Tube | |
| | Roller Clamp | HDPE | Roller Clamp | |
| | Latex Tube | Polyisoprene | Check Valve | |
| | Y Injection Site | ABS | Y Injection Set | |
| | Luer Lock Connector | ABS | Clamp | |
| | Protector Cap of Luer Lock Connector | HDPE | Injection Site | |
| | Needle Hub | PP | Luer Lock Connector | |
| | Needle Tube | Stainless Steel | Infusion Needle | |
| Tubing Diameter | 3.9mm | | Unknown | |
| Filter Characteristics | 15μm | | 15μm | |

| | | |
|---|---|---|
| Needle Gauge | 21G | Unknown |
| Sterile | EO sterilized | Same |
| | $10^{-6}$ | Same |
| Single Use | Single Use | Same |
| Infusion Set Performance | | |
| Particulate contamination | Contamination index limit is less than 90 | Comply with ISO 8536-4 |
| Leakage | No leakage | |
| Tensile strength | Withstand a static tensile force of not less than 15N for 15s | |
| Closure piercing device | Comply the dimension of ISO 8536 | |
| Air-inlet device | Flow of fluid is reduced less than 20% of that from a freely ventilated container | |
| Tubing | Length is not less than 1500mm | |
| Fluid filter | Retention of latex particles is not less than 80% | |
| Drip chamber and drip tube | 20 drops of distilled water delivered by the drip are equivalence to a volume of (1±0.1)ml(1±0.1)g | |
| Flow rate | Deliver not less than 1000ml | |
| Injection site | No leakage | |
| Construction | The clamps can resist the flow of fluid and air at an applied pressure of 50 kPa when closed. | |
| Needle Performance | | |
| Cleanliness | Free from particles and extraneous matter | Comply with ISO 7864 and ISO 9626 |
| Needle length | 38mm | |
| Bond of hub and needle tube | Not broken by the minimum force | |
| Stiffness | Deflection is less than 0.50mm | |
| Dimensions of needle tubing | 0.8mm | |
| Resistance to breakage | The tubing is not break | |

| | | |
|---|---|---|
| Resistance to corrosion | No evidence of corrosion | |
| Biocompatibility | | |
| Cytotoxicity | No Cytotoxicity | Conform with ISO 10993 requirements |
| Intracutaneous Reactivity | No Intracutaneous Reactivity | |
| Skin Sensitization | No Skin Sensitization | |
| Acute Systemic Toxicity | No Acute Systemic Toxicity | |
| Hemolysis | No Hemolysis | |
| Pyrogen | No pyrogen | |

9. Substantially Equivalent (SE) Conclusion

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