May 10, 2024

Shandong Zhushi Pharmaceutical Group Co., Ltd
% Bruce Cai
Technical Manager
Humiss Inc.
RM62, No. 236, Renmin Road, Qingcun Town, Fengxian District
Shanghai, 201414
China

Re: K232475
Trade/Device Name: Disposable infusion set with needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: February 2, 2024
Received: April 11, 2024

Dear Bruce Cai:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,

and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K232475

Device Name

Disposable infusion set with needle

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 under the action of gravity.

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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**510(k) SUMMARY**

The assigned 510(k) number: K232475
Date prepared: May. 10, 2024

## I. SUBMITTER

Manufacturer name: Shandong Zhushi Pharmaceutical Group Co., Ltd.
Address; No. 6, Shande Road, Shan County, Heze City, Shandong Province, 274300, China
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## II. Correspondent Contact Information

Bruce Cai (Contact Person)
**Humiss Inc.**
Tel: +86-13585598660
E-mail: cc401vip@126.com

## III. DEVICE

| | | |
|---|---|---|
| Trade Name: | - | Disposable infusion set with needle |
| Common Name | - | Intravascular Administration Set |
| Classification Name | - | Intravascular administration set |
| Regulation Number | - | 21CFR 880.5440 |
| Regulation Number | - | FPA |

## IV. PREDICATE DEVICE

Predicate Device 510k number: K163160
Predicate device trade name: sterile single-use infusion set
Predicate device common name: Intravascular Administration Set
Predicate Device Manufacturer: JiangXi HongDa Medical Equipment Group Ltd. (No. 39 South Shengli Road, Jinxian County, Nanchang, CN 331700)

## V. Device Description

**Table 5.1. Device Description Summary for Disposable infusion set with needle**

| Models | Subject Device |
|---|---|
| Product name | Disposable infusion set with needle |
| Indications 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 under the action of gravity. |

| | |
|---|---|
| Model name | SY03 |
| Configuration | Protective Cap of Closure-piercing Device<br>Closure-piercing Device<br>Clamp<br>Fluid channel (tubing)<br>Drip chamber upper cover (including the dropper)<br>Drip chamber<br>Drip chamber base (including Fluid Filter membrane)<br>Flow regulator<br>Regulator wheel<br>Luer Lock Connector<br>Infusion needle hub<br>Needle tube<br>Plastic needle handle<br>Infusion needle protector<br>Integral air-inlet with air filter and closure<br>Tubing<br>Lubricant<br>Adhesives |
| Tubing Diameter | 4 mm |
| Filter Characteristics | 15μm |
| Needle Gauge and Lengths | 0.4mm(27G) x13.5mm, 0.45 mm (26 G) x13.5 mm, 0.45 mm (26 G) x15 mm, 0.5mm (25 G) x17.5mm, 0.55mm (24 G) x17.5 mm, 0.55mm (24 G) x20 mm, 0.6 mm (23 G) x22.5 mm, 0.6 mm (23 G) x25 mm, 0.7 mm (22 G) x19 mm, 0.7 mm (22 G) x22.5 mm, 0.7 mm (22 G) x25 mm, 0.8 mm (21 G) x19 mm, 0.8 mm (21 G) x28 mm, 0.9 mm (20 G) x26 mm, 0.9 mm (20 G) x28 mm, 1.1 mm (19G ) x 38 mm, 1.2mm (18 G) x19 mm, 1.2mm (18 G) x26 mm, 1.2mm (18 G) x30 mm, 1.2mm (18 G) x38 mm |
| Sterility condition | EO Sterilized, $10^{-6}$ |

**VI. Predicate Comparison**

<table>
<tr><td>Item</td><td colspan="2">Predicate Device K163160</td><td colspan="2">Subject Device</td><td>Comparison</td></tr>
<tr><td>Product Code</td><td colspan="2">FPA</td><td colspan="2">FPA</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td colspan="2">21 CFR 880.5440</td><td colspan="2">21 CFR 880.5440</td><td>Same</td></tr>
<tr><td>Indication for Use</td><td colspan="2">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.</td><td colspan="2">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 under the action of gravity.</td><td>Same</td></tr>
<tr><td rowspan="13">Configuration and material</td><td>Component name</td><td>Material</td><td>Component name</td><td>Material</td><td rowspan="13">Difference 1</td></tr>
<tr><td>Protector Cap of Spike</td><td>HDPE</td><td>Protector Cap of Spike</td><td>PE</td></tr>
<tr><td>Spike</td><td>ABS</td><td>Spike</td><td>ABS</td></tr>
<tr><td>Air Vent</td><td>PVC</td><td>Air Vent</td><td>PVC</td></tr>
<tr><td>Drip Chamber</td><td>PVC</td><td>Drip chamber</td><td>PVC</td></tr>
<tr><td>Fluid Filter</td><td>ABS</td><td>Drops of bucket</td><td>ABS, Fluid Filter membrane made by Polyethersulfone filtration membrane (PES)</td></tr>
<tr><td>Flexible Tube</td><td>PVC</td><td>Flexible Tube</td><td>PVC</td></tr>
<tr><td>Roller Clamp</td><td>HDPE</td><td>Regulating wheel</td><td>ABS</td></tr>
<tr><td>Latex Tube</td><td>Polyisoprene</td><td>Latex Tube</td><td>N/A</td></tr>
<tr><td>Y Injection Site</td><td>ABS</td><td>Y Injection Site</td><td>N/A</td></tr>
<tr><td>Luer Lock Connector</td><td>ABS</td><td>Luer lock Connector</td><td>PVC</td></tr>
</table>

| | | | | | |
|---|---|---|---|---|---|
| | Protector Cap of Luer Lock Connector | HDPE | Protector Cap of Luer Lock Connector | / | |
| | Needle Hub | PP | Needle hub | PVC | |
| | Needle Tube | Stainless Steel | Needle tube | Stainless steel | |
| Tubing Diameter | 3.9mm | | 4 mm | | Difference 2 |
| Filter Characteristics | 15μm | | 2μm, 3μm, 5μm | | Difference 3 |
| Needle Gauge | 21G | | 18G, 19G, 20G, 21G, 22G, 23 G, 24G, 25G, 26G, 27G | | Difference 4 |
| Sterile | EO sterilized | | EO sterilized | | Same |
| | $10^{-6}$ | | $10^{-6}$ | | Same |
| Single Use | Single Use | | Single Use | | Same |
| Infusion Set Performance | | | | | |
| Particulate contamination | Contamination index limit is less than 90 | | Contamination index limit is less than 90 | | Same |
| Leakage | No leakage | | No leakage | | |
| Tensile strength | Withstand a static tensile force of not less than 15N for 15s | | Can withstand a static tensile force of 15 N for 15s | | |
| Closure piercing device | Comply the dimension of ISO 8536-4 | | Comply the dimension of ISO 8536-4 | | |
| Air-inlet device | Flow of fluid is reduced less than 20% of that from a freely ventilated container | | Flow of fluid is reduced less than 20% of that from a freely ventilated container | | |
| Fluid filter | Retention of latex particles is not less than 80% | | 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 | | 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 | | Deliver not less than 1000ml | | |
| Construction | The clamps can resist the | | The clamps can resist the | | |

| | | | |
|---|---|---|---|
| | flow of fluid and air at an applied pressure of 50 kPa when closed. | flow of fluid and air at an applied pressure of 50 kPa when closed. | |
| Needle Performance | | | |
| Cleanliness | Free from particles and extraneous matter | Free from particles and extraneous matter | Same |
| Needle length | 38mm (meet ISO 7864:2016 Clause 4.10 of 21G needle) | 20.72mm (meet ISO 7864:2016 Clause 4.10 of 23G needle) | Same |
| Bond of hub and needle tube | Not broken by the minimum force | Not broken by the minimum force | Same |
| Stiffness | Deflection is less than 0.50mm | Deflection is less than 0.50mm | Same |
| Dimensions of needle tubing | 0.8mm (meet ISO 9626:2016 Clause 5.6 of 21G needle) | 0.627mm (meet ISO 9626:2016 Clause 5.6 of 23G needle) | Same |
| Resistance to breakage | The tubing is not break | No breakage | Same |
| Resistance to corrosion | No evidence of corrosion | No corrosion | Same |
| Biocompatibility | | | |
| Cytotoxicity | No Cytotoxicity | No Cytotoxicity | Same |
| Intracutaneous Reactivity | No Intracutaneous Reactivity | No Intracutaneous Reactivity | |
| Skin Sensitization | No Skin Sensitization | No Skin Sensitization | |
| Acute Systemic Toxicity | No Acute Systemic Toxicity | No Acute Systemic Toxicity | |
| Hemolysis | No Hemolysis | No Hemolysis | |
| Pyrogen | No pyrogen | No pyrogen | |

**VII Substantial Equivalence Discussion**

The indications for use statement for the Disposable infusion set with needle subject device is equivalent to the predicate device. There are no technological differences between the predicate and subject devices except for the following: Components and materials, Tubing Diameter, Filter Characteristics, and Needle Gauge.

- Difference 1: The subject device has different components and materials compared to the predicate device, such as the predicate device's Injection Site, which the subject device doesn't have. These differences have no adverse effect on clinical safety and performance. The subject device was tested in accordance with ISO 8536-4 and ISO 10993. The requirements of the standards are met.
- Difference 2: The subject device has a different Tubing Diameter compared to the predicate device; predicate device's Tubing Diameter is 3.9 mm, subject device's Tubing Diameter is 4 mm. This slight difference has no adverse effect on clinical safety and performance. The subject device was tested in accordance with ISO 8536-4. The requirements of the standards are met.
- Difference 3: The subject device has different Filter Characteristics compared to the predicate device; predicate device's Filter size is 15μm, subject device's Filter size is 2μm, 3μm, 5μm. This difference has no adverse effect on clinical safety and performance. The subject device was tested in accordance with ISO 8536-4, and USP NF <788>. The requirements of the standards are met.
- Difference 4: The subject device has different Needle Gauges compared to the predicate device, predicate device's Needle Gauge is 21 G, subject device's Needle Gauges are 18G, 19G, 20G, 21G, 22G, 23 G, 24G, 25G, 26G, 27G. This difference has no adverse effect on clinical safety and performance. The subject device was tested in accordance with ISO 8536-4, ISO 7864, ISO 9626 which is same as predicate device. The requirements of the standards are met.

**VIII. Performance Testing**

The Disposable infusion set with needle described in this summary were tested and demonstrated to be in conformance with the following standards:

- ISO 8536-4:2019 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed
- ISO 7864:2016 Fourth Edition: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods;
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- USP NF <788> Particulate Matter in Injections
- USP NF <161> Bacterial endotoxin test
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood

- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-2:2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980:2011 Standard Guide or Accelerated Aging of Sterile Barrier Systems for Medical Devices
- F1140/F1140M-13 (Reapproved 2020) e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

The Disposable infusion set with needle is considered in the category of "External Communicating Devices" and are in contact for a period less than 24 hours with "Indirect blood path" or "Circulating blood" (needles). Thus, hemocompatibility (ISO 10993-4:2017), cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), acute systemic toxicity (ISO 10993- 11:2017), irritation (ISO 10993-23:2021) were carried out for the device in question.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject device met all design specifications as Substantially Equivalent (SE) to the predicate device. The tests conducted for this submission include:

Physical, Mechanical and Chemical Tests performed on the subject devices:

ISO 8536-4:2019
ISO 8536-14:2016
ISO 7864:2016
ISO 9626:2016
ISO 80369-7:2021

Particulate matter:
USP-NF<788>

Sterile Barrier Packaging Testing performed on the subject device:

| | |
|---|---|
| Seal strength | ASTM F88/F88-09 |
| Internal pressure | ASTM F1140/F1140M-13 |
| Dye Penetration | ASTM F 1929-15 |

Sterilization and Shelf-Life Testing performed on the subject device:

| | |
|---|---|
| EO residue | ISO 10993-7:2008 |
| ECH residue | ISO 10993-7:2008 |
| Bacteria Endotoxin Limit | USP NF <161> |
| Shelf-Life Evaluation | Physical, Mechanical, Chemical, Package and Sterility Tests were performed on accelerated aged 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.

**IX. Clinical Test Conclusion**

No clinical trials were conducted in support of this 510(k).

**X. Conclusion**

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