April 12, 2024

Shandong Ande Healthcare Apparatus Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co, Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K222766
Trade/Device Name: Disposable Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 11, 2024
Received: March 11, 2024

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 (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,

Porsche Bennett

Porsche Bennett
for 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.

510(k) Number *(if known)*
K222766

Device Name
Disposable Extension Set

Indications for Use *(Describe)*
The device is used for the administration of fluids from a container into the patient's vascular system through a vascular access device. The intended populations include adults and pediatrics except neonates.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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."

K222766- 510(k) Summary

Date of Preparation: 04/12/2024

1. Sponsor Identification

Shandong Ande Healthcare Apparatus Co., Ltd.
No. 999, Zunxian Road, New & Hi-Tech Zone, Zibo, 255086 Shandong, P. R. China

Establishment Registration Number: 3012039263

Contact Person: Xiaolei Tian
Position: R&D Director
Tel: +86-533-3917821
Fax: +86-533-3143085
Email: tianxiaolei@andemed.com

2. 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: 360-925-3199
Email: info@mid-link.net

3. Identification of Subject Device

Trade Name: Disposable Extension Set
Common Name: Disposable Extension Set
Regulation Name: Intravascular administration set
Regulatory Class: II;
Product Code: FPA;
Regulation Number: 21 CFR 880.5440
Review Panel: General Hospital;

Indication for Use Statement:
The device is used for the administration of fluids from a container into the patient's vascular system through a vascular access device. The intended populations include adults and pediatrics except neonates.

4. Identification of Predicate Device

510(k) Number: K101958
Product Name: AMSINO I.V. ADMINISTRATION AND EXTENSION SETS
Manufacturer: AMSINO International, Inc

Indications for Use:
The AMSINO® I.V. ADMINISTRATION EXT'ENSION SET is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

5. Device Description

The proposed device is a single used device. It includes 30 models. For the 30 different models, each configuration comprises of various components which may include: Male luer lock and protector, Female luer lock and protector, Tube, Flow regulator, Clamp, multiple ways connector, Precision Liquid filter, Needle free connector, Check valve, Graduated flow regulator, Injection site and stopcock. The detail description of models is provided in Table 1.

The proposed devices are sterilized by EO to achieve a SAL 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years.

Table 1 Description of Models

No	Model (REF)	Configuration description
1	C2900000A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 2000mm)
2	C2900002B	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID:

		1.0mm; L: 2000mm)
3	C2900003A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 2000mm), Flow Regulator
4	C2900005B	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 100mm), slide clamp
5	C2900007A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 100mm), Slide Clamp
6	C2900200B	Bi-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 1000mm), Slide Clamp
7	C2900300B	Tri-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 1400mm), Slide Clamp
8	C2900201A	Bi-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp
9	C2900301A	Tri-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1400mm), Slide Clamp
10	C2960009B	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 1500mm), Slide Clamp, 0.2μm Liquid filter
11	C2950010B	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 1500mm), Slide Clamp, 1.2μm Liquid filter
12	C2960011A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, 0.2μm Liquid filter
13	C2950012A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, 1.2μm Liquid filter
14	C2962003A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp, 0.2μm Liquid filter, Needle free connector
15	C2952004A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp, 1.2μm Liquid filter, Needle free connector
16	C2902006A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 200mm), Slide Clamp, Needle free connector
17	C2902202A	Bi-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp, Needle free connector
18	C2902301A	Tri-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1400mm), Slide Clamp, Needle free connector
19	C2902007B	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L: 100mm), Slide Clamp, Needle free connector
20	C2902008A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp. Needle free connector
21	C2902201B	Bi-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 2.3mm; ID: 1.0mm; L:230mm), Slide Clamp, Needle free connector
22	C2902300B	Tri-fuse I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 42.3; ID: 1.0mm; L: 320mm), Slide Clamp, Needle free connector
23	C2904000A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, Needle free connector, check valve
24	C2905000A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 150mm), Slide Clamp, Stopcock
25	C2903000A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp, Graduated flow regulator
26	C2903001A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, Graduated flow regulator, injection site
27	C2903002A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, Graduated flow regulator, Needle free connector
28	C2901000A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1000mm), Slide Clamp, injection site

29	C2961001A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, 0.2μm Liquid filter, injection site
30	C2951002A	I.V. Extension Set with Male Luer lock, Female Luer lock, Tubing (OD: 4.1mm; ID: 3.0mm; L: 1500mm), Slide Clamp, 0.2μm Liquid filter, injection site

6. Substantially Equivalent (SE) Comparison

Table 2 Comparison with K101958

Item	Proposed Device K222766	Predicate Device K101958	Remark
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	Same
Product Code	FPA	FPA	Same
Class	II	II	Same
Indications for Use	The device is used for the administration of fluids from a container into the patient's vascular system through a vascular access device. The intended populations include adults and pediatrics except neonates.	The AMSINO® I.V. ADMINISTRATION EXT'ENSION SET is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.	Same
Models	C2900000A, C2900002B, C2900003A, C2900005B, C2900007A, C2900200B, C2900300B, C2900201A, C2900301A, C2960009B, C2950010B, C2960011A, C2950012A, C2962003A, C2952004A, C2902006A, C2902202A, C2902301A, C2902007B, C2902008A, C2902201B, C2902300B, C2904000A, C2905000A, C2903000A, C2903001A, C2903002A, C2901000A, C2961001A, C2951002A	No product models were exposed in K101958 510(k) summary	Different, Comment 1
Main Configuration/Components	Male luer lock Female luer lock	Luer adapter/connectors	Different, Comment 2

		Slide clamp	Clamp	
		Injection set	latex-free injection port	
		Tubing	Tubing	
		Flow regulator	Flow controller	
		Graduated flow regulator		
		0.2μm/1.2μm Liquid filter	Filter	
		Needle free connector	Needleless injection port	
		Stopcock	Stopcock	
		3-way connector, 4-way connector	Manifold	
		/	Flash bulb	
		/	Y-site	
		/	Drip chamber	
Single Use		Single Use	Single Use	Same
Prescription Use		Yes	Yes	Same
Total Length		100mm~2000mm	Unknown	Different, Comment 3
Tubing diameters		ID:1.0mm,OD:2.3mm ID:3.0mm,OD:4.1mm	Smallbore Standard Bore	Different, Comment 4
Priming Volume		0.23ml ~13.25ml	Unknown	Different, Comment 3
Patient Contact Materials	Male luer lock	Acrylonitrile Butadiene Styrene (ABS)	Unknown	Different, Comment 5
	Female luer lock	Acrylonitrile Butadiene Styrene (ABS)		
	Injection set	Acrylonitrile Butadiene Styrene (ABS) Polyisoprene Rubber		
	Tubing	Poly Vinyl Chloride (PVC)		
	Flow regulator	Acrylonitrile Butadiene Styrene (ABS)		
	Graduated flow regulator	Acrylonitrile Butadiene Styrene (ABS) Silicon Rubber		
	Liquid filter	Acrylonitrile Butadiene Styrene (ABS) Polyether sulfone (PES) Poly Tetra Fluoro Ethylene (PTFE)		

	Needle free connector	Polycarbonate (PC) Silicon Rubber		
	Stopcock	Acrylonitrile Butadiene Styrene (ABS)		
	3-way connector, 4-way connector	Poly Vinyl Chloride (PVC)		
Biocompatibility	Cytotoxicity		Cytotoxicity	Different, Comment 6
	Skin Sensitization		Skin Sensitization	
	Intracutaneous Reactivity		Irritation,	
	Acute Systemic Toxicity		Acute Systemic Toxicity	
	Pyrogen Test		/	
	Hemolysis Test		Hemocompatibility Test	
Performance Standard	ISO 8536-4 ISO 8536-11 ISO 8536-12 ISO 8536-13 ISO 8536-14 ISO 80369-7 ISO 80369-20		ISO 8536-4 ISO 8536-11 ISO 8536-12 ISO 8536-13 ISO 8536-14 ISO 594-1 ISO 594-2	Different, Comment 7
Sterilization method	EO sterilization		EO sterilization	Same
Shelf life	5 years		Unknown	Different, Comment 8

Comment 1 –Models

The proposed device has 30 models, the predicate device didn't include product model information in K101958, 510(k) summary. This difference does not raise different questions of safety and effectiveness.

Comment 2 – Main Configuration/Components

The proposed device only includes extension sets, while the predicate device includes administration sets and extension sets. The main configurations of the proposed device are similar as those of the extension sets of predicate device. However, the components of the proposed device are included in predicate device. Moreover, all configurations are broadly used throughout the medical industry, and their functions are the same or similar. Performance tests have been completed on the proposed device and the test results demonstrate that the device does not raise different questions of safety and effectiveness.

Comment 3 -Total Length and Priming Volume

The total length and priming volume of the proposed device may be different from those of the predicate device. Performance tests have been completed on the proposed device and the test results demonstrate that the device does not raise different questions of safety and effectiveness.

Comment 4 - Tubing diameters

The tubing diameters of the proposed device may be different from those of the predicate device. Performance tests have been completed on the proposed device and the test results demonstrate that the device does not raise different questions of safety and effectiveness.

Comment 5 & Comment 6- Patient Contact Materials & Biocompatibility

The patient contact materials for predicate device are different from those of the predicate devices. However, biocompatibility testing was performed on the proposed device. The data demonstrates there is no adverse effect from the material. Therefore, this difference in the patient contact material does not raise different questions of safety and effectiveness.

Comment 7 - Performance Standard

Both ISO 80369-7 and ISO 80369-20 of the proposed device and ISO 594-1 and ISO 594-2 of predicate device are used to specify the requirements on conical fitting with a 6% (Luer) taper for intravascular or hypodermic applications. ISO 594-1 and ISO 594-2 is superseded by ISO 80369-7. The subject device was adequately tested to currently recognized performance standards for the device type.

Comment 8 - Shelf life

The predicate device's shelf life is unknown. The subject device performance has been adequately tested over the proposed shelf life. In addition, the expiration date of the product is included in the product labels to inform the end user of the shelf life. Therefore, this difference does not raise different questions of safety and effectiveness.

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device.

Performance testing:

The extension tube performance testing and connector testing were conducted on the proposed device; the test results demonstrated that the proposed device complies with the following standards:

- ISO 8536-4:2019 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed
- ISO 8536-12:2007/AMD 1:2012 Infusion equipment for medical use — Part 12: Check valves

- ISO 8536-13:2016 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
- ISO 8536-14:2016 Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

Particular Matter:

The particular matter testing was conducted on the subject device, the test results demonstrated that the proposed device complies with the following standard:

- USP <788> Particular Matter in Injections.

Sterilization:

EO/ECH residual testing was conducted on the proposed device per ISO 10993-7 Amendment – 1 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019).

Shelf life:

A maximum shelf life of 5 years has been assigned to the proposed device. In order to demonstrate substantial equivalence between the subject and predicate device, the sponsor conducted accelerated aging on the proposed device and performed the following tests on the accelerated aged device to provide data for the device shelf life:

- Package integrity of aged device;
- Product performance testing

Packaging integrity:

The package integrity performances of the proposed sterility maintenance package include visual inspection, seal strength and dye penetration resistance. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration.
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Shipping:

A simulated transportation testing was conducted on the proposed device per ASTM D4169-22.

Biocompatibility:

The exposure period of proposed device does not exceed 7 days, blood path, indirect contact, limited contact. Based on the above identified contact level and contact duration, it was tested for Cytotoxicity (ISO 10993-5), Skin Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10), Acute Systemic Toxicity (ISO 10993-11), Pyrogen (ISO 10993-11), and Hemolysis (ISO 10993-4), subacute toxicity testing (ISO 10993-11).

Endotoxin limit:

Endotoxin limit is established as 20 USP Endotoxin Unit (EU) for the proposed device. Test has been conducted by Limulus Amebocyte Lysate (LAL) method according to USP <85> Bacterial Endotoxin Limit.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Disposable Extension Set is substantially equivalent to the AMSINO IV Administration and Extension Sets, K101958, with respect to indications for use, treatment method, and technological characteristics.