May 4, 2026

Amsino International Inc.
Jane Gao
VP of R&D and RA
708 Corporate Center Drive
Pomona, California 91768

Re: K252543
Trade/Device Name: AMSafe Administration Set (BA-70075, BA-70071-D, BA-70070, BA-70071-P, BA-70072, BA-70072-F, BA-70071-DF, BA-70071-DF-120, FE01, FE04)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: April 3, 2026
Received: April 3, 2026

Dear Jane Gao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 -S

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)*
K252543

Device Name
AMSafe Administration Set (BA-70075, BA-70071-D, BA-70070, BA-70071-P, BA-70072, BA-70072-F, BA-70071-DF, BA-70071-DF-120, FE01, FE04)

Indications for Use *(Describe)*
The administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.
The administration set is to be used with patients, 18 years of age or older.
The administration set is to be used under direct supervision of a physician or other certified healthcare provider in healthcare facilities, including but not limited to, hospitals (outpatients only), skilled nursing facilities, and short-term acute care facilities. The administration set is also intended to be used in inpatient rehabilitation facilities and in home settings.
The administration set can be used with the Zyno Z-800F and Z-800WF Infusion pumps or can be administered by gravity flow.

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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K252543 - 510(k) Summary

a) Submitter Information:

Submitter:
Amsino International Inc.
708 Corporate Center Drive
Pomona, CA 91768
Phone: 909-626-5888
Fax: 909-626-3888

Contact Person:
Jane Gao
VP of R&D and RA of Amsino International
Cell phone: 909-992-7892
Jane_gao@amsino.com

Date of Summary: May 1st, 2026

b) Device Information:

Device Trade Name:	AMSafe Administration Set (BA-70075, BA-70071-D, BA-70070, BA-70071-P, BA-70072, BA-70072-F, BA-70071-DF, BA-70071-DF-120, FE01, FE04)
Common or Usual Name:	IV Administration Set
Classification Name:	Intravascular Administration Set
Regulation Number:	21 CFR 880.5440
Device Class:	II
Product Code:	FPA
Review Panel:	General Hospital

c) Identification of Legally Marketed Device(s):

Zyno Medical Administration Sets, 510(k) number K120685.

d) Device Description:

The AMSafe Administration Set is a single use, latex-free, non-DEHP device sterilized with Ethylene Oxide gas. It is utilized to administer fluids from a container to a patient's vascular system through a catheter or needle inserted into a vein.

The AMSafe Administration Set is available for dedicated use with the Zyno Z-800F and Z-800WF Infusion System pumps which are legally cleared to the market under K071545, K100705 and K130690 or they can administer fluids by gravity flow.

Depending on configuration, the device may include the following components: tubing, protective cap(s)

drip chamber with spike, back check valve, needleless Y-sites(s), slide clamp(s), roller clamp(s), pinch clamp(s), 0.2micron filter, 0.22micron filter or 1.2micron filter, male or female luer lock (with cap).

e) Indications for Use:

The administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.
The administration set is to be used with patients, 18 years of age or older.
The administration set is to be used under direct supervision of a physician or other certified healthcare provider in healthcare facilities, including but not limited to, hospitals (outpatients only), skilled nursing facilities, and short-term acute care facilities. The administration set is also intended to be used in inpatient rehabilitation facilities and in home settings.
The administration set can be used with the Zyno Z-800F and Z-800WF Infusion pumps or can be administered by gravity flow.

Intended use
The administration set is intended to deliver antibiotics, parental fluids and other infusion fluids compatible with PVC tubing

f) Substantial equivalence discussion:

Comparison between subject device and predicate device.

Table 1: Intended use comparison:

Device Characteristics	AMSafe Administration Set (Subject device)	Zyno Medical Administration Sets K120685 (Predicate device)	Assessment of Differences
Classification	II	II	Same
Product Code	FPA	FPA	Same
Indications for Use	The administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein. The administration set is to be used with patients, 18 years of age or older.	Zyno Medical Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.	The intended use, intended target population, intended user and environment of use are same. The subject device has a more detailed description of the indications for use than that of predicate.

	The administration set is to be used under direct supervision of a physician or other certified healthcare provider in healthcare facilities, including but not limited to, hospitals (outpatients only), skilled nursing facilities, and short-term acute care facilities. The administration set is also intended to be used in inpatient rehabilitation facilities and in home settings. The administration set can be used with the Zyno Z-800F and Z-800WF Infusion pumps or can be administered by gravity flow.		
Prescription/over-the counter use	For Rx only	For Rx only	Same

Table 2: Technological characteristics comparison:

Technological Characteristics	**AMSafe Administration Set (Subject device)**	**Zyno Medical Administration Sets K120685 (Predicate device)**	**Assessment of Differences**
Operating Principle	The administration sets deliver the intravenous infusions via an infusion pump or gravity	The administration sets deliver the intravenous infusions via an infusion pump or gravity	Same
Sterilization and sterility assure level	EtO Sterilization SAL 10^{-6}	EtO Sterilization SAL 10^{-6}	Same

Non-Pyrogenic	Yes	Yes	Same
Shelf life	3 years	3 years	Same
Single Use/Reusable	Single Use	Single Use	Same
Priming volume	Approx. 18mL, 19mL and 20mL based on difference configurations Approx. 9mL for secondary set	Approx. 18mL, 19mL and 20mL based on difference configurations Approx. 9mL for secondary set	Same
Drops/ml	20	20	Same
Set length	105” (266cm) for primary administration set 40” (101cm) for secondary set	105” (266cm) for primary administration set 40” (101cm) for secondary set	Same
Internal and external diameter	2.67mm and 3.79mm	2.67mm and 3.79mm	Same
Components			
Spike with air vent	Yes	Yes	The shape of spike and cap of air vent color is different. The spike with air vent is an industry standard component which is compliant to ISO 8536-4 standard.
Drip chamber	Yes	Yes	The shape of drip chamber is different. The drip chamber is an industrial standard component which is compliant to ISO 8536-4 standard.
Pump segment (tubing ID/OD/Length and pinch clamp)	Yes	Yes	Same

Needleless Y injection site	Yes	Yes	The design and color are different. The needleless Y injection site used in the subject device is a cleared device with 510(k) K173665.
Male Luer Lock Adapter	Yes	Yes	Same
Flow regulator	Yes	Yes	The shape and color of clamps are different. The roller clamp and slide clamp used in the subject device are industry standard components which are compliant to ISO 8536-4 standard.
Back check valve	Yes	Yes	The shape and color are same; the supplier is different. The component is sourced from different suppliers. The back check valves used in the subject device is industry standard component which are compliant to ISO 8536-4.
Flow filter	Yes	Yes	The filter size is same; the component is sourced from different suppliers. The flow filter used in the subject device is industry standard components which are compliant with related standard.
Pressure activated valve	No	Yes	Different. The subject device does not include the pressure activated valve. The performance testing demonstrates that the subject device meets

			the specification without this component.

Discussion:
The subject device and predicate device are different with respect to the following items:

• Description of Indications for use: the subject device has more detailed description on the indications for use than that of predicate.
The indications for use for subject devices clarify the scope of the use population, users and use environment etc. No new indications are added.

• Components: the spike, drip chamber, needleless Y injection site and roller clamp are different compared to the predicate (e.g. shape, color, suppliers), these components were all industry standard components which are compliant to ISO 8536-4 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed, MOD. These components are also used in the legally cleared devices under K173665, K093773 or K973107. Back check valve and flow filters are sourced from different suppliers. These components are industry standard components which are compliant to ISO 8536-4. The subject device does not include the pressure activated valve.

Appropriate performance tests and biocompatibility tests were performed on the representative samples of subject devices to demonstrate the subject devices meet all the established specifications and related standards, the difference between the subject devices and predicate devices will not impact the safety and effectiveness.

g) Summary of Non-clinical Testing:
The non-clinical testing for AMSafe Administration Set was performed to demonstrate verification testing in conformance with the acceptance criteria and support the substantial equivalence.

Performance testing:
The following basic performance testing was conducted to support the substantial equivalence determination:

- ISO 8536-4-19 Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed, MOD and ISO 8536-8-15 Infusion equipment for medical use- Part 8: Infusion sets for single use with pressure infusion apparatus
    - o Leakage
    - o Tensile Strength
    - o Storage Tube Volume
    - o Closure-piercing Device Testing
    - o Air-inlet Device Testing
    - o Tubing Testing
    - o Drip Chamber and Drip Tube Testing
    - o Flow Regulator: Clamp Opening and Closing
    - o Protective Cap Testing
    - o Flow rate of infusion fluid under gravity feed
    - o Chemical Performance Testing
- ANSI/AAMI CN27 General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications

    - o General requirements for luer activated valves
- USP<788> Particulate Matter in Injections
    - o Particulate Testing
- USP<71> Sterilitytests and <85> Bacterial endotoxins test
    - o Microbiological performance testing
- Pump Segment Compatibility Testing with Infusion Pump
    - o Flow rate accuracy testing: AAMI TIR101:2021 Fluid delivery performance testing for infusion pumps
    - o Alarm detection testing

Sterilization, Packaging, Shelf-life testing:

- ISO 11135-18 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
  Sterilization was achieved by ethylene oxide and meets the requirements of ISO11135. The ethylene oxide sterilization method achieves a Sterilization Assurance Level (SAL) of 10^{-6}.
- ISO 11607-1 & 2 -19 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems and Packaging for terminally sterilized medical devices and ASTM D4169-22
  Sterile Barrier and Packaging Systems and Simulated Transportation
  ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  The shelf life of the final finished sterilized device was evaluated according to the recognized consensus standard ASTM F1980-21 to verify that the subject device will remain within specification during the prescribed shelf life when stored under the labeled storage conditions.

Biocompatibility Testing

- ISO 10993-1-18 Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process following the FDA Guidance: "Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within risk management process", the tests selected were for prolonged, blood path indirect, externally communicating devices. The following biocompatibility tests were successfully conducted on the representative samples of AMSafe Administration Set:
    - o Acute Systemic Toxicity
    - o Hemolysis
    - o Irritation
    - o Sensitization
    - o Cytotoxicity
    - o Pyrogens
    - o Subacute/Subchronic toxicity

h) Clinical Testing:

Clinical testing was not required for this submission.

i) Conclusions on Substantial Equivalence:

The different technological characteristics between the subject and predicate device are evaluated in bench performance testing, pump segment compatibility testing, packaging integrity, accelerated aging and biocompatibility tests conducted on the subject device of AMSafe Administration Set was

designed to compare its safety and effectiveness directly against the predicate device, Zyno medical administration set.

In accordance with the guidance regarding technological characteristics, the subject device incorporates different components as different shape, color or suppliers. These differences were specifically evaluated during this test battery to ensure they do not introduce new safety concerns or negatively impact device performance.
The results of the test demonstrate the following:

Safety:
The subject device exhibited biocompatibility regarding the shape, color or suppliers change from the biocompatibility test that are comparable to the predicate device. The toxicological risk associated with the device is considered low according to the chemical characterization test on the subject device. This confirms that the difference of shape, color or suppliers change does not compromise materials related concerns or introduce new risks.

Effectiveness:
Performance metrics regarding delivery accuracy when used with intended pumps, leakage, bonding strength, packaging integrity, sterility and stability under designed shelf life demonstrate that the subject device achieves its intended use equivalently to the predicate. For example, flow rate accuracy and time-to-alarm, drop/mL, flow filter performance and all physical, chemical and biological performance which all fall within the acceptable range defined by the predicate device's performance within the designed shelf-life. This confirms that the difference in shape, color or suppliers change does not compromise performance related concerns or introduce new risks.

Conclusion
The data obtained from this non-clinical test battery confirms that the technological differences between the subject device and the predicate device do not raise new questions of safety or effectiveness.

The AMSafe Administration Set is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate devices.

The conclusions drawn from the nonclinical tests demonstrate that the AMSafe Administration Set is as safe, as effective, and perform as well as the legally marketed predicate device cleared under K120685.