October 7, 2022

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

Re: K220267
Trade/Device Name: AMSafe® NeuFlo™ Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: September 9, 2022
Received: September 9, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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.
For Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220267

Device Name
AMSafe® NeuFloTM Needleless Connector

Indications for Use *(Describe)*
The AMSafe® NeuFloTM Needleless Connector are intended to use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

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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K220267 510(k) Summary

a)Submitter information:

Preparation Date: 09/09/2022
Manufacturer's Name: Amsino International Inc.
708 Corporate Center Drive, Pomona, CA91768
Correspondions official : Jane Gao
VP of R&D and RA
Mobile: +86 139 1614 7664
Email Address: Jane_gao@amsino.com

b) Device information:

Trade Name: AMSafe® NeuFlo™ Needleless Connector
Common or Usual Name: Needless connector
Regulation Name: Intravascular administration set
Regulation Number: 21 CFR 880.5440
Product Code: FPA
Device Class: Class II

c)Identification of legally marketed devices:

- Predicate device: Clave Connector by ICU Medical Inc. [K970855]

d) Device Description:

AMSafe® NeuFlo™ Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set.

e)**Indication for Use:**

The AMSafe® NeuFlo™ Needleless Connector are intended to use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

f)Substantial Equivalence Discussion

The table below includes a comparison of the intended use and technological characteristics between the new device and those of the predicate device:

Characteristic	Subject Device AMSafe NeuFlo Needleless Connector	Predicate Clave Connector (K970855)	Discussion between Subject device and Predicate device
Indications for use	The AMSafe NeuFlo Needleless Connector are intended to use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.	As an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.	Same
Prescription only or over the counter	Prescription only	Prescription only	Same
Product Code	FPA	FPA	Same
Technological	The design principle is the	The design principle is the	Same

Characteristic	Subject Device AMSafe NeuFlo Needleless Connector	Predicate Clave Connector (K970855)	Discussion between Subject device and Predicate device
Characteristics	split septum silicone seal covers internal hollow blunt spike, seal is compressed upon a Luer activation, and hollow blunt spike is formed the fluid pathway	split septum silicone seal covers internal hollow blunt spike, seal is compressed upon a Luer activation, and hollow blunt spike is formed the fluid pathway	
Principle of operation	The device is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It is used as injection site when accessed by attaching a male luer connector to the device. All the operations are usual, clockwise rotation is for locking, and anticlockwise rotation is for disconnecting.	The device is a sterile single patient use connector for needleless access to the IV line and/or IV catheter during IV therapy. It is used as injection site when accessed by attaching a male luer connector to the device. All the operations are usual, clockwise rotation is for locking, and anticlockwise rotation is for disconnecting.	Same
Materials of main components	Housing: Polycarbonate	Housing: Polyester	Different. The housing and spike material is different between predicate and subject device. The finished sample of subject device has been conducted biocompatibility test according to ISO10993 standard
	Seal: Silicone	Seal: Silicone	
	Spike: ABS	Spike: Polycarbonate	
	Cap: Polypropylene	Cap: Polypropylene	
Performance testing	The Luer adapter is compliance with ISO80369-7	The Luer adapter is compliance with ISO80369-7	Same
	Flow rate at 1m head height is more than 1000mL in 10 mins per ISO8536-4	Flow rate at 1m head height is more than 1000mL in 10 mins per ISO8536-4	Same
	No leakage per ISO8536-4 & ISO8536-8	No leakage per ISO8536-4 & ISO8536-8	Same
	Microbial ingress testing: infected bacterial suspension deliberately, simulated clinical use, swabbed access port and incubated filtered fluid, the incubated results should show that the swabbing	Microbial ingress testing: infected bacterial suspension deliberately, simulated clinical use, swabbed access port and incubated filtered fluid, the incubated results should show that the swabbing	Same

Characteristic	Subject Device AMSafe NeuFlo Needleless Connector	Predicate Clave Connector (K970855)	Discussion between Subject device and Predicate device
	was effective, or the device has ability to resist bacterial invasion.	was effective, or the device has ability to resist bacterial invasion.	
Biological evaluation	Conform with ISO10993 series requirements	Conform with ISO10993 series requirements	Same
Single use/reusable	Single use	Single use	Same
Sterile method	ETO sterilization $SAL10^{-6}$	$SAL10^{-6}$	Different. Not sure the sterilization method for predicate, but SAL between subject and predicate is same. The subject device is used with validated sterilization process.
Shelf life	5 years	Not sure	Different. The subject device has passed the accelerated 5years aging test.

The subject device is same in both indications for use and technological characteristics when compared to the predicate device, the difference is the material, sterilization method and shelf life. However, this difference does not affect the performance and safety of the device as evidenced by the performance, stability and biocompatibility verification testing conducted on the subject device.

g) Summary of Non-clinical testing (Bench)

The non-clinical testing for The AMSafe NeuFlo Needleless Connector was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

The following performance testing was conducted on the finished device.

Test	Method	Acceptance criteria	Conclusion
Physical Performance test			
Leakage Test	ISO8536-4	ISO8536-4	Pass
Luer adapter connection	ISO80369-7	ISO80369-7	Pass
Free Flow rate	ISO8536-4	ISO8536-4	Pass
Particulate contamination	ISO8536-4	ISO8536-4	Pass
Chemical performance test			

Reducing matter	ISO8536-4	ISO8536-4	Pass
Metal ions	ISO8536-4	ISO8536-4	Pass
Titration acidity or alkalinity	ISO8536-4	ISO8536-4	Pass
Residue on evaporation	ISO8536-4	ISO8536-4	Pass
UV absorption of extract solution	ISO8536-4	ISO8536-4	Pass
EO residual test	ISO10993-7	≤10μg/g	Pass
Biological performance test			
Sterility test	ISO8536-4	ISO8536-4	Pass
Pyrogenicity	ISO8536-4	ISO8536-4	Pass
Biocompatibility test			
In vitro cytotoxicity test	ISO10993-5	ISO10993-5	Pass
Skin sensitization test 0.9% sodium chloride injection extract	ISO10993-10	ISO10993-10	Pass
Skin sensitization test sesame oil extract	ISO10993-10	ISO10993-10	Pass
Intracutaneous reactivity test 0.9% sodium chloride injection extract	ISO10993-10	ISO10993-10	Pass
Acute systemic toxicity test sesame oil extract	ISO10993-11	ISO10993-11	Pass
Pyrogen test 0.9% sodium chloride injection extract rabbit	ISO10993-11	ISO10993-11	Pass
Bacteria endotoxins test Gel-Clot technique	USP 43-NF <85>	USP 43-NF <85>	Pass
Subchronic systemic toxicity test	ISO10993-11	ISO10993-11	Pass
In Vitro hemolytic properties test	ISO10993-4	ISO10993-4	Pass

The shelf life of the final finished sterilized device was evaluated according to the recognized consensus standard ASTM F1980-16 to verify that the subject device will remain within specification during the prescribed 5 years shelf life when stored under the labeled storage conditions.

h) Conclusions:

Based on a comparison of technological characteristics, intended use between subject device and predicate, and performance test results, we conclude that AMSafe NeuFlo Needleless Connector is as safe and effective and is substantially equivalent to the predicate device.