September 5, 2018

Amsino International, Inc.
Cathy Hong
Senior RA Specialist
708 Corporate Center Drive
Pomona, California 91768

Re: K173665
Trade/Device Name: AMSafe® Sure-LokTM Needle-Free Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 7, 2018
Received: August 9, 2018

Dear Cathy 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA
Geeta K.
Pamidimukkala -S

for 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173665

Device Name
AMSafe® Sure-Lok™ Needle-Free Connector

Indications for Use *(Describe)*
The AMSafe® Sure-Lok™ Needle-Free Connector is an accessory to an Intra-vascular Administration Set used as a secondary sterile injection site for delivery of fluids to a patient's vascular system through a cannula inserted into a 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."*

# Section 5: 510(k) Summary (K173665)

- **Submitter Information**

Submitter: Amsino International Inc.
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Contact Person: Cathy Hong
Senior RA Specialist
Phone: +86(21)-69117118
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E-mail: Cathy_Hong@amsino.com
Date Prepared: 9/5/2018

- **Device Information**

Common or Usual Name: Needle-Free Connector
Trade or Proprietary Name: AMSafe® Sure-Lok™ Needle-Free Connector (AY0200S)
Regulation Number: 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Panel: General Hospital
Product Code: FPA

- **Predicate Device Information**

Device Name: NAC PRN Needleless Access Connector
510(k) Number: K992268

- **Device Description:**

The AMSafe® Sure-Lok™ Needle-Free Connector is a Needle-Free connector intended for single patient use, for direct injection, intermittent infusion, continuous infusion or aspiration of drugs, blood and fluids used as an accessory

to an Intravascular administration set without the use of a needle, thus eliminating the risk of needlestick injuries. The AMSafe® Sure-Lok™ Needle-Free Connector is a closed, Luer activated device that allows for negative fluid displacement.

The AMSafe® Sure-Lok™ Needle-Free Connector individually packaged is supplied as a sterile, non-pyrogenic, single use, disposable device.

- **Indications for Use**

The AMSafe® Sure-Lok™ Needle-Free connector is an accessory to an intra-vascular Administration Set used as a secondary sterile injection site for delivery of fluids to a patient's vascular system through a cannula inserted into a vein.

- **Product Comparison Summary**

The proposed AMSafe® Sure-Lok™ Needle-Free Connector is equivalent to the Kipp Group's NAC PRN Needleless Access Connector. The proposed device has the same operation principle, the same materials and the same general characteristics with the predicate device. The indications for use of the proposed device is similar with the predicate device, "or artery" is removed as standard clinical practice does not include normal administration of fluids into artery.

The design and materials of the proposed devices are identical to the predicate device (K992268).

| No. | Device Characteristic | Proposed Device | Predicate Device | Results |
|---|---|---|---|---|
| 1 | **Product Code** | FPA | FPA | Same |

| | | | | |
|---|---|---|---|---|
| 2 | Indications for Use | The AMSafe® Sure-Lok™ Needle-Free connector is an accessory to an intra-vascular Administration Set used as a secondary sterile injection site for delivery of fluids to a patient's vascular system through a cannula inserted into a vein. | The NAC PRN Needleless Access Connector is an accessory to an Intravascular Administration Set used as a secondary sterile injection site for delivery of fluids to a patient's vascular system through a cannula inserted into a vein or artery. | Similar |
| 3 | **Regulation Number** | 880.5440 | 880.5440 | Same |
| 4 | **Design Configuration** |  |  | Similar |
| 5 | **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. And it is also used as adapter when connecting to a female Luer connector. All the operations are usual, | 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. And it is also used as adapter when connecting to a female | Same |

| | | | | |
|---|---|---|---|---|
| | | clockwise rotation is for locking, and anticlockwise rotation is for disconnecting. | Luer connector. All the operations are usual, clockwise rotation is for locking, and anticlockwise rotation is for disconnecting. | |
| 6 | **Materials of main components** | | | |
| | Top cover | polycarbonate | polycarbonate | Same |
| | Housing | polycarbonate | polycarbonate | |
| | Valve Plug | Silicone | Silicone | |
| | Protective cap | Polypropylene | Polypropylene | |
| 7 | **Single Use/ Reusable** | Single patient use | Single patient use | Same |
| 8 | **Primary package** | Poly pouch with Medical dialysis paper | Poly pouch with Medical dialysis paper | Same |
| 9 | **Sterile method** | EO Sterile | EO Sterile | Same |

- **Performance Data**

The AMSafe® Sure-Lok™ Needle-Free Connector met the acceptance criterion for all functional, microbial ingress, sterility, biocompatibility and other performance criteria which verify it to be substantially equivalent to the predicate device.

Bench testing of the proposed devices is performed. Luer performance testing is conducted according to *ISO 80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications* which is replacement to ISO 594-2: 1998 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock.* Testing was also provided according to ISO 594-2:1998.

| Testing Items | Test Criteria |
|---|---|
| Visual inspection | Conform with the internal criteria |
| Leakage test | Conform with ISO 8536-4 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1 (2013)<br><br>Conform with ISO 8536-8: 2015 Infusion Equipment for Medical Use - Part 8: Infusion Sets for Single Use with Pressure Infusion Apparatus |
| Compatible with MLL fitting | Section 3: Dimensions and tolerances in ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -Part 2: Lock fittings) |
| Sealing performance | Section 4.2: leakage in ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -Part 2: Lock fittings) |
| Free Flow Rate | Conform with ISO 8536-4:2010 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1 (2013) |
| Liquid leakage | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Air leakage | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Separation force | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Stress cracking | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Unscrewing torque | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Ease of assembly | Section 5.6: Ease of assembly in ISO 594-2:1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -Part 2: Lock fittings) |
| Resistance to overriding | Conform with ISO80369-7: 2016 Small-Bore Connectors For Liquids And Gases In Healthcare Applications - Part 7: Connectors For Intravascular or Hypodermic Applications |
| Weld strength test | Conform with the internal criteria |

Sterility was assessed in accordance to ISO 11135:2007, Sterilization of Health

Care Products-Ethylene Oxide and ISO 10993-7: 1995 and 2008, Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide sterilization residuals.

Microbial ingress testing was conducted to an internal standard.

Biocompatibility for the AMSafe® Sure-Lok™ Needle-Free Connector was assessed in accordance with *ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. According to Section 5 of ISO 10993-1: 2009, the proposed device is classified as a "External communicating device, Blood path, indirect (>24 hours to 30 days)." Based on the assessment of the device, the following tests were performed:

| **Testing Items** | **Test Criteria** |
|---|---|
| Cytotoxicity | ISO 10993-5: 2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity |
| Sensitization | ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization |
| Intracutaneous Reactivity Test | ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization |
| Acute systemic toxicity | ISO 10993-11: 2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity |
| Haemolysis | ASTM F 756-13: Standard Practice for Assessment of Hemolytic Properties of Materials |
| Pyrogenicity | ISO 10993-11: 2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity |
| Subchronic Toxicity | ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity |

Results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the AMSafe® Sure-Lok™ Needle-Free connector.

- **Conclusions**

The information provided within this pre-market notification demonstrates that the AMSafe® Sure-Lok™ Needle-Free Connector is substantially equivalent to the predicate device.