March 30, 2018

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

Re: K171857
Trade/Device Name: AMSure® Enteral Feeding Syringe with ENFit Tip
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: February 27, 2018
Received: February 28, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171857

Device Name
AMSure® Enteral Feeding Syringe with ENFit Tip

Indications for Use *(Describe)*
The AMSure® Enteral Feeding Syringe with ENFit Tip is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in adults only.

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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Section 5: 510(k) Summary

1 Submitter Information

Submitter: Amsino International Inc.
708 Corporate Center Drive, Pomona CA 91768, USA

Contact Person: Cathy Hong
Senior RA Specialist of Amsino Medical Group
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Date Prepared: March 28, 2018

2 Device Information:

Common or Usual Name: Enteral Feeding Syringe with ENFit Tip
Trade or Proprietary Name: AMSure® Enteral Feeding Syringe with ENFit Tip
Regulation Number: 876.5980
Regulation Name: Gastrointestinal Tubes and Accessories
Regulatory Class: II
Product Code: PNR

3 Identification of Legally Marketed Device(s)

Device Name: Monoject™ Enteral Feeding Syringe with ENFit Connector
510(k) Number: K160419

4 Device Description:

The AMSure® Enteral Feeding Syringes with ENFit Tip are standard piston style syringes consisting of a syringe barrel with ENFit syringe nozzle, syringe plunger, syringe stopper and protective cap. The devices are made with polypropylene and polyisoprene rubber. The plunger can be linearly pulled and pushed along the inside wall of the barrel, allowing the syringe to take in and expel fluid through the nozzle at the front end of the barrel.

The integral syringe nozzle has a female ENFit connector designed to be compatible only with enteral access devices or accessories having ENFit compliant or

compatible male connectors to form a dedicated system that prevents wrong-route administration of fluids.

The Enteral Feeding Syringes with ENFit Tip have a capacity of 60mL for single-use. The devices are provided either sterilized by EtO or non-sterile.

The enteral syringe to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in adults only.

5 Indications for Use

The AMSure® Enteral Feeding Syringe with ENFit Tip is indicated for use as a dispenser, a measuring device, and a fluid transfer device. It is used to deliver fluids into the gastrointestinal system of a patient who is physically unable to eat and swallow. The enteral syringes are intended to be used in clinical or home care settings by users ranging from laypersons (under the supervision of a clinician) to clinicians in adults only.

6 Product Comparison Summary

The proposed AMSure® Enteral Feeding Syringe with ENFit Tip and the predicate device are intended for patients who require enteral nutrition due to illness or injury which prevents normal chewing and swallowing. These products are enteral syringes that have the same intended use, similar indications for use, the same function, and the same general characteristics.

The technological characteristics of the proposed devices are substantially equivalent to the predicate Monoject™ Enteral Feeding Syringe with ENFit Connector (K160419).

Four of the six syringe models are non-sterile and are for single patient use for up to 8 uses within 24 hours when cleaned according to the cleaning instructions provided in the Instructions for Use. The cleaning procedure was validated according on FDA's 2015 Guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", and also tested to demonstrate the same performance after cleaning (8 washes within 24 hours) as the predicate device (K160419). The difference from the predicate device (cleaning procedure) does not impact safety and effectiveness. The performance of the proposed device is substantially equivalent to the predicate device.

7 Nonclinical Testing

The following performance testing was conducted on the proposed device:

a) Biocompatibility Testing:

Cytotoxicity, Sensitization and Irritation testing have been conducted per ISO 10993-5 and ISO 10993-10. The Biocompatibility testing demonstrated the biological safety of the proposed devices which may indirectly contact the patients.

b) Performance Testing:

- Tests of syringe tip (ENFIT) per ISO 80369-3:
  - Dimensional analysis
  - Enteral Connector Misconnection assessment
  - Fluid leakage
  - Stress Cracking
  - Resistance to separation from axial load
  - Resistance to separation from unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing
  - Dose accuracy
- Tests conducted for syringe per ISO 7886-1:
  - Appearance performance
  - Capacity Tolerance
  - Graduated Scale
  - Critical Dimension
  - Freedom from air and liquid leakage
  - Tolerance on graduated capacity
  - Dead space
  - Piston/plunger assembly (Piston sliding, Piston Fit in Barrel)
  - Silicone oil quantity
  - Chemical (Limits for acidity or alkalinity, Limits for extractable metals)
  - Ink adhesion
- Additional testing:
  - Stability testing

- Sterilization validation
- Package testing
- Dose accuracy testing
- Risk management
- Usability testing (for cleaning instructions)
- Cleaning validation for reprocessing
- Performance testing following 8 uses and washes within 24 hours

Performance testing conclusion: The results of the performance evaluation tests showed the AMSure Enteral Feeding Syringe with ENFIT Tip passed all acceptance criteria.

8 Conclusions

The information provided within this pre-market notification demonstrates that the AMSure® Enteral Feeding Syringe with ENFit Tip is substantially equivalent to predicate devices. Performance testing supports that the technological differences do not change the safety or effectiveness profile of the device as compared to the predicate devices.