November 10, 2022

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

Re: K220230
Trade/Device Name: AMSure Enteral Feeding Pump and Feeding Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZH
Dated: October 12, 2022
Received: October 12, 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
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)*
K220230

Device Name
AMSure® Enteral Feeding Pump

Indications for Use *(Describe)*

The AMSure® Enteral Feeding Pump is intended to work with the disposable enteral feeding sets to deliver nutritional formula to the gastrointestinal system of adult patients who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing.

Only intended for adult patients, not for pediatric use.

The AMSure® Enteral feeding pump is intended to be used in healthcare facilities by licensed healthcare professional users only.

The AMSure® Enteral feeding pump is for use only with Amsino AMSure® feeding sets.

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.

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510(K) SUMMARY

Preparation Date: 11/8/2022
Manufacturer's Name: Amsino International Inc.
708 Corporate Center Drive, Pomona, CA91768
Correspondions official : Jane Gao
VP of R&D and RA of Amsino
Mobile: +86 139 1614 7664
Email Address: Jane_gao@amsino.com

Trade Name: AMSure® Enteral Feeding Pump and Feeding Set
Common or Usual Name: Enteral Feeding Pump and Set
Regulation Name: Infusion Pump
Regulation Number: 21 CFR880. 5725
Product Code: LZH
Device Class: Class II

Predicate Device(s): SENTINEL Enteral Feeding pump (K011587)

Device Description:
The AMSure® enteral feeding pump is intended to work with the disposable enteral feeding sets that deliver formula via rotary peristaltic pumping system to provide nutrition for those who do not have the ability to orally ingest food

Indication for Use:
The AMSure® Enteral Feeding Pump is intended to work with the disposable enteral feeding sets to deliver nutritional formula to the gastrointestinal system of adult patients who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing.
Only intended for adult patients, not for pediatric use.
The AMSure® Enteral feeding pump is intended to be used in healthcare facilities by licensed healthcare professional users only.
The AMSure® Enteral feeding pump is for use only with Amsino AMSure® feeding sets.

Substantial Equivalence Discussion
Intended use comparison

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

Characteristic	Subject Device: AMSure Enteral feeding pump K220230	Predicate: SENTINEL Enteral feeding pump K011587	Discussion between subject device and predicate
Indications for use	The AMSure® Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula to the gastrointestinal system of adult patients who are physically unable to eat and swallow or who are unable to get sufficient nutrition through eating and swallowing. Only intended for adult patients, not for pediatric use. The feeding pump and feeding sets are intended to be used in healthcare facilities by licensed healthcare professional users only. The AMSure® Enteral feeding pump is for use only with Amsino AMSure® feeding sets.	The enteral feeding pump accurately controls the flow of liquid feeding solution to patients who are unable or unwilling to consume adequate nutrients. Liquid feedings may consist of commercially prepared formulas or blenderized foods and are most often delivered by means of nasogastric, nasoduodenal of nasojenjunal feeding tubes. In some cases, a surgically placed esophagostomy, gastrostomy or enterostomy tube may be used. The pump is not intended for use with blood or blood products. The pump is not for intravenous delivery.	No differences

Prescription only or over the counter	Prescription only	Prescription only	No differences
Intended population	Adult	Adult, pediatric	Different Subject device for adults uses only, not for pediatric use
Environment of use	Healthcare facilities	Healthcare facilities	No differences

Discussions of differences in indications for use statement:
The subject device has same indications for use with the predicate, but not for pediatric use. This difference does not raise different questions of safety and effectiveness than the predicate device.

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

Characteristic	Subject Device: AMSure Enteral feeding pump and feeding set	Predicate: SENTINEL Enteral feeding pump K011587	Discussion between subject device and predicate
Design (pump)	The pump incorporates a menu-controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options.	The pump incorporates a menu-controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options.	Different. The hardware and software are different. The subject device contains 2 separate MCUs, and each MCU embeds a specific software in order to secure the pump's running. These differences do not raise different questions of safety and effectiveness than the predicate device.
Mode of Action	Tubing in tension against rotor	Tubing in tension against rotor	
Motor type	Stepper motor	Stepper motor	
Sensors and flow monitoring alarms	The device incorporates 3 sensors. Infrared for • Upstream occlusion/empty bag • Free flow Ultrasonic for • Air in line Pressure sensors for • Downstream occlusion	The device incorporates 1 sensor. Infrared sensors for • Upstream occlusion/empty bag • Free flow	The subject device has added an ultrasonic sensor to detect air in line alarm based on bubble accumulation calculation; also added a pressure sensor to detect downstream occlusion and distinguish upstream or downstream occlusion. The predicate device has one infrared sensor to monitor all the flow related events including occlusion/empty bag/free flow. The alarms of subject device have been verified and the results passed the criteria. These differences do not raise different questions of safety and effectiveness than the predicate device.
Pump control alarms	• Upstream Tube Alarm • Downstream Occlusion • Free Flow • Air in Line • Feeding Complete • Out of Battery • Battery Error • Motor Error • Communication Fault • Total power failure alarm • Single Dose Complete • Low Battery • Battery Degradation • No Operation	• Feeding complete • Single dose complete • Low battery • Out of battery • Battery error • Motor error • Communication fault • No operation	Different The subject device has more control alarms than the predicate.
Display	Color 4.3" LCD touch screen	4-digit LED	Different The subject device has a larger and clearer touch screen. These

Characteristic	Subject Device: AMSure Enteral feeding pump and feeding set	Predicate: SENTINEL Enteral feeding pump K011587	Discussion between subject device and predicate
			differences do not raise different questions of safety and effectiveness than the predicate device.
Self-test	Automated self-tests at system start-up	No	Different. The self-test at system start-up to check the functioning of major components, motor, sensors etc. In case of component failure, the pump pop-up warning information and the pump cannot be used. These differences do not raise different questions of safety and effectiveness than the predicate device.
Maximum occlusion pressure	11 psi	15 psi	Different. The occlusion pressure of subject device is lower than the predicate. These differences do not raise different questions of safety and effectiveness than the predicate device.
Electrical Safety Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 62304 IEC 62366	UL544	Different The subject device is designed to follow the currently recognized standards. These differences do not raise different questions of safety and effectiveness than the predicate device.
EMC/ EMI and ESD standards	IEC 60601-1-2	IEC601-1-1-2	
Degree of Protection against Electrical Shock	Class 2 Type BF per IEC Standards Pass	Class 2 Type BF Pass	
Degree of Protection for liquid ingress	IPX4 Pass	IPX1 Pass	Different The subject device has higher level of liquid ingress protection than the predicate. These differences do not raise different questions of safety and effectiveness than the predicate device.
Enclosure	Flame retarded plastic	Flame retarded plastic	
Power adapter	Yes	Yes	
Power requirement	100-240VAC, 50-60Hz	120VAC,60Hz	
Rechargeable battery	Lithium-ion	Sealed lead acid	Different The subject device is using Lithium-Ion battery. This difference does not raise safety and effectiveness than the predicate device.
Battery life	7 hours at 120 mL/h	12 hours at 125 mL/h	Different The subject device has shorter battery life than predicates. These differences do not raise different questions of safety and effectiveness than the predicate device.

Characteristic	Subject Device: AMSure Enteral feeding pump and feeding set	Predicate: SENTINEL Enteral feeding pump K011587	Discussion between subject device and predicate
Battery recharge time	5hr	10hr	Different The recharge time of subject device is much shorter than the predicate's
Battery operation indicator	Yes	Yes	
Feeding mode	Both continuous mode and intermittent mode.	No	Different The subject device has intermittent feed mode, but the predicate doesn't have. These differences do not raise different questions of safety and effectiveness than the predicate device.
Flow range	1-400 mL/hr in 1 mL increments	5-295 mL/hr in 1mL increments	Different. The subject device has a wider flow rate range to meet the update market needs. These differences do not raise different questions of safety and effectiveness than the predicate device.
Volume range	1-9999 mL 1 mL increments	Adjustable 1-2000 mL 1 mL increments, and 2000-9999ml in 5ml increments	Different. The subject device has a smaller increment. These differences do not raise different questions of safety and effectiveness than the predicate device.
Flow rate accuracy	±10% of selected rate under normal or worst-case condition	±10% of selected rate under normal or worst-case condition	
Auto prime	Yes – flow rate 1200 mL/h	No	Different The subject device has auto prime function, but the predicate doesn't have this function . These differences do not raise different questions of safety and effectiveness than the predicate device.
Pump weight	2.38pounds	5.2pounds	Different The pump weight of subject device is less than the predicate's. These differences do not raise different questions of safety and effectiveness than the predicate device.
Pump size	5.2"x4.3"x6.7"	7.5"x9"x5.2"	Different The pump size of subject device is less than the predicate's. These differences do not raise different questions of safety and effectiveness than the predicate device.
Pole clamp mountable	Yes	Yes	
RFID	Yes	No	Different As an optional feature, the subject device incorporates RFID technology. These differences do not raise different questions of safety and effectiveness than the predicate device.
KTO	Yes	No	Different As an optional feature, KTO feature may help maintain tube patency during the pump stop interval. The KTO feature has

Characteristic	Subject Device: AMSure Enteral feeding pump and feeding set	Predicate: SENTINEL Enteral feeding pump K011587	Discussion between subject device and predicate
			been verified to meet the specifications, this difference does not raise different questions of safety and effectiveness than the predicate device.
Operating Temperature Range	16°-40°C (60.8°-104°F)	16°-40°C (60.8°-104°F)	
Storage Temperature Range	-20°- 60°C (-4°-140°F)	-10°- 50°C (14°-122°F)	Different The subject device has wider storage temperature range. These differences do not raise different questions of safety and effectiveness than the predicate device.
Anti-free flow	Yes	Yes	No differences

Performance Tests:

A safety assurance case as recommended by the FDA guidance document, "Infusion pumps total product life cycle" was provided for the AMSure® Enteral Feeding Pump and Feeding Set.

The stated top-level goal of the safety assurance case is the pump and set are adequately safe for its intended use.

The following specific evidence were included within the assurance case to demonstrate that the subject device is verified and validated for its intended use and to demonstrate substantial equivalence to the predicate devices.

Software	Software verification and validation per FDA guidance for the "Content of premarket submissions for software contained in medical devices" for a Major Level of Concern and FDA guidance document "Infusion pump total product life cycle"
Electrical safety	The electrical safety evaluation of the medical electrical equipment was performed per standards IEC60601-1 medical electrical equipment part1: General requirements for basic safety and essential performance, IEC60601-1 Canadian and US national differences test.
EMC	The AMSure® pump was evaluated to IEC 60601-1-2: Medical electrical equipment-Part 2: General requirement for basic safety and essential performance - Collateral standard: electromagnetic compatibility - Requirements and tests.
Device performance	The essential performance requirements of the device (including feeding sets) were verified through performance testing in accordance with the intended use of the device and in accordance with the FDA Guidance "Infusion Pumps Total Product Life Cycle" including: •Performance testing of essential performance attributes •Reliability testing •Flow rate accuracy testing across all operating conditions •Alarm detection
Human factors	Follow FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016), the human factors studies were conducted with the intended user population, use environment, and use scenarios to simulate clinical conditions. Results of the human factors testing demonstrate validation of the device per the intended use.
Biocompatibility	The biocompatibility test reports provided were conducted per ISO10993 series standard following Good Laboratory Practices and the representative product tested passed all acceptance criteria.

Battery testing	The battery pack has been tested in accordance with IEC 62133.

Clinical Tests

Not Applicable

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The AMSure® Enteral Feeding Pump and Feeding Set is substantially equivalent to the SENTINEL Enteral Feeding pump (K011587) with respect to the indications for use, target populations, treatment method, and technological characteristics.