September 25, 2020

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

Re: K200051
Trade/Device Name: PUGGLE Enteral Feeding Pump and Feeding Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZH
Dated: August 25, 2020
Received: August 27, 2020

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,

Carolyn Dorgan
Acting 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)*
K200051

Device Name
PUGGLE® Enteral Feeding Pump and Feeding Set

Indications for Use *(Describe)*
The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates.
The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to be used in clinical or home care settings by users ranging from laypersons to physicians.
The PUGGLE® Enteral Feeding Pump and Feeding Set shall be used together 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.

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510(K) SUMMARY

Preparation Date:	9/25/2020
Manufacturer's Name:	Amsino International Inc. 708 Corporate Center Drive, Pomona, CA 91768
Corresponding Official:	Jane Gao VP of R&D of Amsino International
Telephone Number:	Mobile: +86 139 1614 7664
Email Address:	Jane_gao@amsino.com
Trade Name:	PUGGLE® Enteral Feeding Pump and Feeding Set
Common or Usual Name:	Enteral Feeding Pump and set
Regulation Name:	Infusion Pump,
Regulation Number:	21 CFR 880.5725
Product Code:	LZH
Device Class:	Class II
Predicate Device(s):	(K143263) Kangaroo™ Connect Enteral Feeding Pump and Connect Feeding Set

Device Description:

The PUGGLE® Enteral Feeding Pump and Feeding Set consists of an enteral feeding pump and 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.

The pump incorporates a graphical interface that walks the users through the PUGGLE® Enteral Feeding Pump and Feeding Set setup feed rates and volumes as well as other feeding options. The PUGGLE® Enteral Feeding Pump and Feeding Set come with three different connector types: standard, ENFit®, and ENFit® with Transition Connector.

Indication for Use:

The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates.

The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to be used in clinical or home care settings by users ranging from laypersons to physicians.

The PUGGLE® Enteral Feeding Pump and Feeding Set shall be used together only.

Substantial Equivalence Discussion

Intended Use Comparison

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

Characteristic	**Predicate Device** Kangaroo™ Connect Enteral Feeding Pump and Set K143263	**Subject Device** PUGGLE® Enteral Feeding Pump and Feeding Set K200051	**Discussion**
Indications for Use	The Kangaroo™ Connect Enteral Feeding Pump with Kangaroo Connect™ Feeding Sets is intended to deliver nutritional formula at a controlled rate to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates. The feeding pump and feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians.	The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to deliver nutritional formula to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates. The PUGGLE® Enteral Feeding Pump and Feeding Set are intended to be used in clinical or home care settings by users ranging from laypersons to physicians. The PUGGLE® Enteral Feeding Pump and Feeding Set shall be used together only.	No differences between the devices
Prescription Only or Over the Counter	Prescription Only	Prescription Only	No differences between the devices
Intended Population	Adult, pediatric	Adult, pediatric	No differences between the devices
Environment of Use	Hospital, home use, ambulatory (ground)	Hospital, home use, ambulatory (ground)	No differences between the devices

Discussions of differences in Indications for Use statement

The PUGGLE® Enteral Feeding Pump and Feeding Set shall be used together only.

Technological Characteristics

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

Features	**Predicate Device** Kangaroo™ Connect Enteral Feeding Pump and Set K143263	**Subject device** PUGGLE® Enteral Feeding Pump and Feeding Set K200051	Explanation of Differences
Technological Characteristics (Pump and Set)	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate	Same.	NA
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 device incorporates ultrasonic sensors to detect the air and blockages in the feeding set	Same.	NA
Flow range	1-600 mL/hour in 1 mL increments	1-400 mL/hour 1 mL increments	The subject device has a narrower flow rate range, but the range remains within the predicate device range.
Volume range	1-3000 mL in 1 mL increments	1-9999 mL 1 mL increments	The subject device has a wider volume range than the predicate device. The subject device maintains performance over the full volume range, as verified through performance testing.
Motor speed	Discontinuous rotation	2 speed modes: Discontinuous 0 to 19 mL/h Continuous rotation 20mL/h	The subject device maintains adequate continuous motor speed as verified through performance testing.
Accuracy	+/- 5% or 0.5 mL/h according to IEC Standard 60601-2-24	+/- 5%	The subject device's flow rate accuracy is consistent at all flow rates as verified through performance testing, not just those outlined in IEC 60601-2-24.
Auto prime	Yes – flow rate 1200 mL/h	Yes – flow rate 600 mL/h	Both devices have auto-prime functionality, with the subject device having a slower rate of prime than the predicate. This does not raise new questions of safety and effectiveness.
Protocol function	Yes, 1 – 99 boluses	Yes, 1- 8 Bolus	The number of programmable bolus functions does not impact the substantial equivalence of the subject device.
Anti-free flow /One-way valve	Yes (opening pressure 3.47 psi)	Yes (opening pressure 2.90 psi)	The opening pressure is lower and was verified

			through performance testing.
Maximum occlusion pressure	20 psi (138 kPa)	16 psi (110 kPa)	The subject device in general has a more sensitive detection of occlusions and raises an occlusion alarm in a shorter period of time than the predicate device. This does not raise different questions of safety or effectiveness based on the risk associated with an occlusion for the intended use of the subject device.
Power adapter	Yes	Same	NA
Display	Color TFT (320x240 pixels)	Color LCD (320x240 pixels)	NA
Battery life	24 hours at 125 mL/h (using power safe mode)	20 hours at 120 mL/h using normal mode[9]	The subject device has a shorter battery life than the predicate device but both have similar rechargeable power sources and alarms for battery life .
Rechargeable battery	Lithium-ion	NiMH	Substantial equivalence of different battery type evaluated through performance testing
Operating Temperature Range	5°-40°C (41°-104°F) at 93% R.H. (non-condensing)	Same	NA
Storage Temperature Range	0°- 50°C (32°-122°F) at 93% R.H. (non-condensing)	Similar: 0°- 40°C (32°-104°F) at 93 % R.H. (non-condensing)	Similar
Medical and Electrical Safety Standards	IEC 60601-1 ANSI/AAMI ES 60601-1 IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-24 IEC 62304 IEC 62366	IEC 60601-1 ANSI/AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-2-24 *not FDA recognized IEC 62304 IEC 62366-1	NA
Degree of Protection against Electrical Shock	Class 2 Type BH per IEC Standards	Same	NA
Degree of Protection for liquid ingress	IP26 per IEC 60529	IP44 per IEC 60529	The ingress protection of IP44 is adequate for the intended use environment of the subject device.
EMC/ EMI and ESD standards	IEC 60601-1-2 Parts 1 and 2	IEC 60601-2:2015	NA

Design (Feeding set)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (14inches) • Cassette containing pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1200ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (12inches) • Cassette containing pump interface module (peristaltic tubing) • Tubing from pump to patient connector (59 inches)	Differences in design do not raise different questions of safety or effectiveness and performance testing verified that this design meets the essential performance requirements.
Feeding Set Connector	Patient connector (ENFit connector compliant to ISO 80369-3)	Patient connector (ENFit connector compliant to ISO 80369-3)	NA
Pump feeding set Materials/Chemical composition	Polyvinyl chloride (PVC): Feeding bags and caps, Tubing Silicone: Peristalitic tubing Polycarbonate: Cassette body CoPolyester: Patient connector ABS: Spike, Tube holder and cap Strontium Ferrite/nylon: Set ID magnets	Polyvinyl chloride (PVC): Feeding bags and caps, Tubing Silicone: Peristalitic tubing ABS: Spike, Tube holder and cap, Cassette body, Patient connector	Differences in materials were evaluated for substantial equivalence through performance and biocompatibility testing.
Drip chamber	No	No	NA
Anti-free flow	Yes	Yes	NA

Performance Testing:

A safety assurance case as recommended by the FDA guidance document, "Infusion Pumps Total Product Life Cycle" was provided for the PUGGLE® Enteral Feeding Pump and Feeding Set.

The stated top level goal of the safety assurance case is:

The pump is acceptably safe for its intended use.

The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments.

The information in the safety assurance case was supplemented by additional test reports and hazard analysis documents to augment the arguments for acceptability of risk mitigations, reliability and device requirements verification and validation to meet the top level goal that the device is safe for its intended use.

The following specific evidence was 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 FDA guidance document "Infusion Pump Total Product Life Cycle"
Cybersecurity	Cybersecurity was evaluated per the FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff," (October 2, 2014) and the risk associated cybersecurity related hazards is determined to be low

Electrical Safety	Electrical Safety testing in accordance with applicable IEC standards (IEC 60601-1:2005 AAMI ES 60601- 1:2005, Medical electrical equipment-Part1: General requirements for basic safety and essential performance)
EMC	Electromagnetic compatibility evaluation in accordance with applicable standards (IEC 60601-1-2:2014, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility Requirements and tests)
Administration Set Compatibility	Verification of the pump essential performance was completed with the indicated administration sets
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: • System Verification and Validation activities • Performance testing of essential performance attributes • Stability testing of feeding set • Flow Rate Accuracy testing across all operating conditions • Downstream Occlusion Detection • Pump Alarms (Air presence, upstream and downstream occlusions, set dislodged, rotor stuck, cassette error)
Battery testing	NiMH battery safety successfully tested per IEC 62133
Human Factors	Human factors studies per the 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.
Reprocessing/Cleaning	AAMI TIR30:2011/R 2016 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
Biocompatibility	Biocompatibility testing as outlined in the FDA Guidance, "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo)" has demonstrated the biological safety of parts of the medical device which may indirectly contact the patient. Stability testing evaluated the properties of the feeding set after accelerated aging in support of the labeling.

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 PUGGLE® Enteral Feeding Pump and Feeding Set is substantially equivalent to the Kangaroo Connect Enteral Feeding Pump with Kangaroo Connect Feeding Sets cleared under K143263 with respect to the indications for use, target populations, treatment method, and technological characteristics.