September 16, 2022

DRW Medical
℅ Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K221676
Trade/Device Name: Exsalta
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 18, 2022
Received: August 18, 2022

Dear Paul Dryden:

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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K221676

Device Name
Exsalta

Indications for Use *(Describe)*
Intended to be used in a medical facility as a means to help evacuate saliva, mucous, vomit or other aspirant from the mouth and/or airway to allow adequate respiration or ventilation of the patient

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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510(k) Summary

Date Prepared: 18-Aug-22

DRW Medical, LLC
2710 Concord Road
Aston PA 19014 USA
Tel - 610-996-5308

Official Contact: Dan Tatum- President

Submission Correspondent: Paul Dryden
ProMedic, LLC
St. Petersburg, FL

Proprietary or Trade Name: Exsalta

Common/Usual Name: Powered Suction Pump
Classification CFR: 21 CFR 878.4780
Classification Code: BTA
Classification Name: Pump, Portable, Aspiration (Manual Or Powered)
Class: Class II

Predicate Device: Medela Vario 8/18/ci Suction Pumps K153663

Device Description:
Exsalta is an AC 110 V powered microprocessor controlled peristaltic suction pump used for clearance of airway secretions. The device is used on a desktop, or shelf. This peristaltic suction pump with touch screen controls is designed for suction procedures where low airflow is desired.

Exsalta (the pump) is a reusable device. The accessories are single use.

Exsalta complies with the following FDA recognized standards:

- AAMI ANSI ES 60601-1: 2005 +A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- ISO 10079-1:2015 Medical suction equipment - Part 1: Electrically powered suction equipment [Including: Amendment 1 (2018)]

Safety Features:
The suction circuit and collection container isolate suction contents from the room and from the pump, providing for safe handling and disposal. The collection container is under positive pressure and has three ports. A first port is where the patient media is pumped into the container. The second port provides an air vent to the atmosphere. The air vent port incorporates a viral filter to protect the atmosphere from patient media. When the container is full the internal liquid float valve closes, and the air vent closes. The third port has a tube that extends to the internal pressure sensor for communication with the microprocessor. When the collection container is full and activates the float valve, the increase in pressure signals the microprocessor to stop the pump.

The pump provides a clinician with the ability to adjust vacuum levels without changing the flowrate. The flow rate is fixed by the ID of the pump tube (6.4mm) and the pump RPMs (400) which is constant. The user may select any vacuum limit from 60-300 mmHg vacuum and the flow rate remains at ~1.4 L/min.

Specifications:
Vacuum: Medium Vacuum, 8-40 kPa, (60-300 mmHg,) low flow – 1.4 L/min at max vacuum. Vacuum measured from Zero level – atmosphere +/- 10%

Electrical: AC-120V, 60 Hz, 2A

Operating/Storage Ranges
Operating: +5°C to +40 °C
Storage: 25°C to +70 °C
Humidity Limits: 15 to 93% RH (non-condensing)
Atmospheric Pressure: 700 hPA-1060 hPA

Indications for Use:
Intended to be used in a medical facility as a means to help evacuate saliva, mucous, vomit or other aspirant from the mouth and/or airway to allow adequate respiration or ventilation of the patient.

Patient Population:
The Exsalta is indicated for patients that may require aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside.

Environments of use:
Medical facilities.

We present the proposed device vs. the predicate in the **Table** below.

Attribute	Predicate Vario 8/18/ci			Proposed Device
Regulation	21CFR 878.4780			21CFR 878.4780
Product Code	BTA – Pump, Portable, Aspiration (manual or powered)			BTA – Pump, Portable, Aspiration (manual or powered)
Indications for Use	The Medela Vario 8/18/ci Suction Pumps are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside. Generally the Medela Vario 8/18/ci is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, gastrointestinal in either "constant" or "intermittent" mode.			Intended to be used in a medical facility as a means to help evacuate saliva, mucous, vomit or other aspirant from the mouth and/or airway to allow adequate respiration or ventilation of the patent
Environment of Use	Professional healthcare facility environment			Professional healthcare facility environment
User Interface				
User Control	On/off switch for Vario 18 / 8 versions On/off/intermittent switch for Vario c/i versions Vacuum regulator, press knob to turn			On / Off switch Touch Panel
Visual Indicator	Vacuum gauge LED for battery operation			Vacuum gauge uses Digital Display Various screens for control, use and maintenance of the device
Accessories	Patient tubing connectors (with and without coupling pieces) Reusable lids, jars Disposable liners Disposable jars Connectors and Tubing Filters			Disposable Connectors and Tubing Disposable Collection jar Disposable Filters
Flow liters/min	Vario 8 / Vario 8 c/I 8 liters/min			1.4 liters/min
Maximum vacuum mmHg/kPa	Vario 8 / Vario 8 c/i -68mmHg -9kPa	Vario 18 - 563mmHg -75kPa	Vario 18 c/i -413 mmHg -55 kPa	60-300 mmHg 8 – 40 kPa

Attribute	Predicate Vario 8/18/ci		Proposed Device
Therapy modes	Vario 8 and Vario 18 Continuous	Vario 8 c/i and Vario 18 c/i Continuous / intermittent	Continuous
Power Source	AC versions: 230-240V, 50/60 Hz, 90 VA 120V, 60 Hz, 70 VA AC/DC versions: 100-240V, 50/60 Hz, 80 VA		AC-120V, 60 Hz, 2A
Electrical Protection Type	Class II		Class I
Ingress	IP21		IP21
Applied Part Type	CF		B
Operating Ambient Temperatures	+5…+40°C		+5 to 40°C
Operating Ambient Humidity	15…93% R.L.		15 to 93% RH
Operating Pressure	70 – 106 kPa		70 to 106 kPa
Storage Ambient Temperatures	-25 to +70°C		-25 to +70°C
Storage Ambient Humidity	15 to 93% RH		15 to 93% RH
Storage Pressure	70 – 106 kPa		70 to 106 kPa
Weight [kg]	7.7lbs (3.5kg) (AC-version) 9.3 lbs (4.2 kg) (AC/DC-Version with NiMH Battery)		12.3 pounds
Dimensions (hxwxd)	15x7x11 inches / 380x170x285 mm		Height 5”, Width 12”, Depth 10”
Principles of Operation			
Suction aggregate type	QuatroFlex™ AC or DC-Motor with flat belt transmission to the four piston/cylinder modules		Peristaltic

Attribute	Predicate Vario 8/18/ci	Proposed Device
Flow control	To adjust the level of suction, the regulator knob has to be pressed inwards and turned in the desired direction. The knob will be locked when it's not pressed down to prevent accidental adjustment. The tubing is clamped and the user can use the gauge to adjust the suction level. When the desired vacuum is reached, the knob can be released.	Touch screen slide bar with digital display of suction level set
Vacuum Regulation type	Mechanical regulator	Microprocessor controlled Proportional valve Mechanical regulator
Vacuum Gauge type	Analog vacuum gauge	Digital vacuum display
Standards	AAMI/ANSI ES60601-1:2005 IEC 60601-1-2: 2007 ISO 10079-1: 2009	AAMI/ANSI ES60601-1:2005 + A1: 2012 IEC 60601-1-2: 2014 ISO 10079-1: 2015

Substantial Equivalence Discussion and Rationale

The table above compares the key features of the proposed device with the identified predicate – Medela Vario 8/18/ci K153663. The comparison demonstrates that the proposed devices can be found to be substantially equivalent.

Indications for Use –
The indications for use are similar for the proposed device when compared to the predicate device.

Discussion – Both devices are indicated for bodily fluids (including vomit) or infectious materials from a patient's airway. Both devices have equivalent range of pressure and flow. Minor difference does not raise different concerns of risk than the predicate.

Technology and construction –
Both devices use electrical power to pump fluids into a reservoir.

Discussion – The subject devices uses a peristaltic pump whereas the predicate uses a piston pump. In either case similar pressures and flow are obtained. The differences do not raise different concerns of safety or effectiveness compared to the predicate.

Environment of Use –
The environments of use for the subject and predicate device are similar, namely clinical settings.

Discussion – The environments of use are identical.

Patient Population –
The patient population is similar to the predicate device.

Discussion – The subject device provides a wide range of control in pressure and flow and will always be used by a trained clinician.

Non-clinical Testing
We performed a number of tests to demonstrate that the proposed device performed as intended. Testing includes:

- Shelf-life / Aging
- Software Verification and Validation
- IEC 60601-1
- IEC 60601-1-2
- ISO 10079-1:2015

The subject device met all performance criteria.

Animal
No animal testing was performed.

Clinical
No human clinical testing was performed.

Discussion of Differences –

There are no significant differences in critical function between the proposed device and the predicate device.

The performance testing has demonstrated that the subject device met the applicable standard performance requirements. The above table plus the risk analysis do not identify any new or different risks compared to the predicate.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.