DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 18, 2016

Medela AG
% Ms. Adrienne Lenz
Pathway Regulatory Consulting, LLC
W324S3649 County Road E
Dousman, Wisconsin 53118

Re: K153663
Trade/Device Name: Vario 8/18/ci
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 29, 2016
Received: May 2, 2016

Dear Ms. Lenz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K153663

Device Name
Vario 8/18/ci

Indications for Use *(Describe)*
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 bed-side.

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.

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

MEDELA AG

VARIO 8/18/CI
SUCTION PUMPS

Medela AG
Vario 8/18/ci Suction Pumps

K153663

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: May 17, 2016

SUBMITTER:

Medela AG
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6341 Baar / Switzerland
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Fax + 41 (0)41 769 51 00

PRIMARY CONTACT PERSON:

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Pathway Regulatory Consulting, LLC
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SECONDARY CONTACT PERSON:

Markus Bütler
Vice President Quality Assurance
Medela AG

DEVICE:

TRADE NAME: Vario 8/18/ci

COMMON/USUAL NAME: Powered Suction Pump

CLASSIFICATION NAMES: 21 CFR 878.4780 Powered Suction Pump

PRODUCT CODE: BTA

PREDICATE DEVICE(S):

K061205, K061435 Medela Vario 8/18/ci

Medela AG
Vario 8/18/ci Suction Pumps

DEVICE DESCRIPTION:

The Medela Vario 8/18/ci suction pump is an AC or AC/DC-powered aspirator and incorporates in its medium sized housing a motor with a flat belt power transmission to the pistons and cylinders, an ON/OFF-switch, a vacuum gauge in kPa and mmHg, a membrane vacuum regulator, an overflow protection device (hydrophobic filter) and connection tubing, an electric cord and an instruction manual.

With its QuatroFlex™ technology, the drive power is transferred to the four piston/cylinder modules by means of high-grade, flexible thin-films hinges. The required suction value is rapidly built-up. High suction performance and low weight are positive features of the Vario pump.

The Models Vario 18 "high vacuum" suction pump have a suction capacity of 18 liters per minute and a maximum vacuum up to -75 kPa (-563 mmHg). The pump is marked "low flow - high vacuum".

The Model Vario 18 c/i "medium vacuum" suction pump has a suction capacity of 18 liters per minute and a maximum vacuum up to -55 kPa (-375 mmHg). The pump is marked "low flow - medium vacuum".

The Models Vario 8 "low vacuum" suction pump have a suction capacity of 8 liters per minute and a maximum vacuum up to -9 kPa (-68 mmHg). The pump is marked "low flow - low vacuum".

A variety of reusable and disposable accessories are available.

INTENDED 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 bed-side.

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.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Vario 8/18/ci Suction Pumps use the same fundamental technology as the predicate pumps. The Vario 8/18/ci indications for use is a subset of the predicate devices indications for use. Additional testing has also been conducted to support expanded specifications. The table

below summarizes the key differences between the Vario 8/18/ci Pumps and the predicate devices.

	Vario 8/18/ci	**Vario 8/18/ci (K061205/ K061435)**
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.	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 and thoracic drainage (in combination with a water seal or dry seal chest drain) in either "constant" or "intermittent" mode. Especially for thoracic drainage the Medela Vario 8 is indicated in situations such as pneumothorax, after surgery (post-operative), thorax injury, pleura effusion, pleuryempyem or other related conditions. The Medela Vario 18 c/i Suction Pump is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. The device is also 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.
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 for Vario 18 / 8 versions On/off/intermittent switch for Vario c/i versions Vacuum regulator, press knob to turn

Medela AG
Vario 8/18/ci Suction Pumps

	Vario 8/18/ci			**Vario 8/18/ci (K061205/ K061435)**		
Visual Indicator	Vacuum gauge LED for battery operation			Vacuum gauge LED for battery operation		
Accessories	• Patient tubing connectors (with and without coupling pieces) • Reusable lids, jars • Disposable liners • Disposable jars • Connectors and Tubing • Filters • Foot Controls (vacuum) • Clamp Holders • Specimen cups • Drainage valve			• Patient tubing connectors (with and without coupling pieces) • Reusable lids, jars • Disposable liners • Disposable jars • Connectors and Tubing • Filters • Foot Controls (vacuum) • Clamp Holders • Specimen cups • Drainage valve		
Flow liters/min	Vario 8 / Vario 8 c/i 8 liters/min	Vario 18 18 liters/min	Vario 18 c/i 18 liters/min	Vario 8 / Vario 8 c/i 8 liters/min	Vario 18 18 liters/min	Vario 18 c/i 18 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	Vario 8 / Vario 8 c/i -68mmHg -9kPa	Vario 18 -563mmHg -75kPa	Vario 18 c/i -413 mmHg -55 kPa
Therapy modes	Vario 8 and Vario 18 Continuous		Vario 8 c/i and Vario 18 c/i Continuous/ intermittent	Vario 8 and Vario 18 Continuous		Vario 8 c/i and Vario 18 c/i Continuous/ intermittent
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 versions: 230-240V, 50/60 Hz, 90 VA 120V, 60 Hz, 70 VA AC/DC versions: 100-240V, 50/60 Hz, 80 VA		
Electrical Protection Type	Class II			Class II		
IP-Protection	IP21			IPX1		

Medela AG
Vario 8/18/ci Suction Pumps

	Vario 8/18/ci	**Vario 8/18/ci (K061205/ K061435)**
Type	CF	Vario AC 8/ AC 18 BF Vario AC/DC 8 /ACDC 18 c/i CF
Operating Ambient Temperatures	+5…+40°C	+5…+40°C
Operating Ambient Humidity	15…93% R.L.	30…75% R.L.
Operating Pressure	70 – 106 kPa	70 – 106 kPa
Storage Ambient Temperatures	-25…+70°C	+5…+40°C
Storage Ambient Humidity	15…93% R.L.	20…95% R.L.
Storage Pressure	70 – 106 kPa	70 – 106 kPa
Weight [kg]	7.7lbs (3.5kg) (AC-version) 9.3 lbs (4.2 kg) (AC/DC-Version with NiMH Battery)	7.7lbs (3.5kg) (AC-version) 9.3 lbs (4.2 kg) (AC/DC-Version with NiMH Battery)
Dimensions (hxwxd)	15x7x11 inches / 380x170x285 mm	15x7x11 inches / 380x170x285 mm
Housing Material	Plastic material ABS	Plastic material ABS
Principles of Operation		
Suction aggregate type	QuatroFlex™ AC or DC-Motor with flat belt transmission to the four piston/cylinder modules	QuatroFlex™ AC or DC-Motor with flat belt transmission to the four piston/cylinder modules

Medela AG
Vario 8/18/ci Suction Pumps

	Vario 8/18/ci	Vario 8/18/ci (K061205/ K061435)
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.	To adjust the level of suction, the regulator knob has to be pressed inwards and turned into 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.
Vacuum Regulation type	Mechanical regulator	Mechanical regulator
Vacuum Gauge type	Analog vacuum gauge	Analog vacuum gauge
Software, AC/DC models only	The complexity of the software is low; only two tasks handle motor on/off switch and rechargeable battery management.	The complexity of the software is low; only two tasks handle motor on/off switch and rechargeable battery management.

SUMMARY OF NON-CLINICAL TESTS:

The Vario 8/18/ci suction pump complies with voluntary standards for electrical safety, electromagnetic compatibility, and powered suction pumps. The following data were provided in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971: 2007.
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since prior to mitigations of hazards, failure of the software could lead to minor injury, such as pain or engorgement.
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005 standard and IEC 60601-1-2: 2007 standards, respectively
- Performance testing demonstrating compliance with EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment

- Vacuum and flow measurements: Performance testing to determine the vacuum levels and flow of the pump as compared to its specifications, which are identical to those of the predicate version of the Vario 8/18/ci pumps.
- Verification of operating times of the Vario AC/DC, if it is powered by battery only. The operating times were checked with different pump loads and battery types. The correct function of the battery low indication was also confirmed. The function is dependent on the antecedent pump settings / work load. The dependency was checked at worst case conditions, therefore completely different pump loads/settings were chosen for each test run. Verification of the reliability of the charging/discharging process in different ambient temperatures was also completed.
- Confirmation of the endurance runtime of the Vario AC/DC is at least the specified 2,600h.
- Confirmation that the sound emission of the pumps is below the maximum specification.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Vario 8/18/ci suction pump to its predicate device.

CONCLUSION:

The differences between the Vario 8/18/ci suction pumps and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Vario 8/18/ci suction pumps are substantially equivalent to the legally marketed predicate device.