May 4, 2021

Medline Industries, Inc.
Kelsey Closen
Regulatory Affairs Specialist
Three Lake Drive
Northfield, Illinois 60093

Re: K203135
Trade/Device Name: Medline Vacu-line Suction Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: March 30, 2021
Received: April 1, 2021

Dear Kelsey Closen:

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 and Part 809); 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203135

Device Name
Medline Vacu-line Suction Aspirator

Indications for Use *(Describe)*
The Medline Vacu-line Suction Aspirator is a portable, AC-powered device to be used on general patient population excluding neonatal due to pressure range, to supply a vacuum source adequate within the stated operating vacuum range, to aspirate fluidsfrom respiratory airway. Intended use in home care or hospital environments.

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
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Kelsey Closen
Regulatory Affairs Specialist
Phone: 847-949-2283
Email: KClosen@medline.com

Summary Preparation Date
May 4, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Vacu-line Suction Aspirator
Common Name: Powered suction pump
Classification Name: Pump, Portable, Aspiration (manual or powered)
Product Code: BTA
Classification Panel: General & Plastic Surgery
Regulatory Class: II
Regulation Number: 21 CFR 878.4780

Predicate Device
EasyGoVac
K140179

Device Description
Medline Vacu-line Suction Aspirator is an AC powered medical suction aspirator that is intended to remove saliva, thick mucus and other secretions from the patient's airway or respiratory system. The device is intended to be used by healthcare facilities and in homecare. The device is small in size, lightweight and easy to carry allowing it to be portable. The main structure of the suction device

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includes vacuum pump, vacuum gauge, pressure regulating valve, and is to be used in conjunction with accessories like suction tubing, air filters, and canisters (these accessories are outside the scope of this submission). The Medline Vacu-line Suction Aspirator is a non-sterile device and can be used on multiple patients when following the proper cleaning techniques detailed in the instruction for use, but the accessories are all single patient use and should be disposed of properly and in accordance with their respective instructions for use. The device is a high vacuum/low flow with a vacuum gauge of minimum vacuum range 21.15 ± 4.86 kPa to maximum vacuum range 82.84 ± 1.84 kPa, 2.5 grade and a flow rate of ≥14L/min. The power supply for the device is AC 120 voltage (60Hz) and can be used continuously for up to 30 minutes. The device has a sound level of 66.81 ± 1.37 dB in an open atmosphere and 68.42 ± 0.93 dB in a closed atmosphere. The canister bottles are 850cc, single patient use and disposable. This devices uses an Inline Hydrophobic filter that has a pore size of 0.45 microns; the filter blocks bacteria from entering the vacuum and it will prevent liquid from entering the vacuum pump and tubing.

Indications for Use

The Medline Vacu-line Suction Aspirator is a portable, AC-powered device to be used on general patient population excluding neonatal due to pressure range, to supply a vacuum source adequate within the stated operating vacuum range, to aspirate fluids from respiratory airway. Intended use in home care or hospital environments.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Vacu-line Suction Aspirator	EasyGoVac	N/A
510(k) Reference	K203135	K140179 (model PM66AC)	N/A
Product Owner	Medline Industries, Inc.	Precision Medical	N/A
Product Code	BTA	BTA	Same
Intended Use	The Medline Vacu-line Suction Aspirator is a portable, AC-powered device to be used on general patient population excluding neonatal due to pressure range, to supply a vacuum source adequate within the stated operating vacuum range, to aspirate fluids from respiratory airway. Intended use in home care or hospital environments.	The Easy Go Aspirator provides a portable, AC powered medical vacuum source. It is intended for use in the homecare / health care environments.	Same

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Regulation Number	878.4780	878.4780	Same
Design Features	-Disposable canisters (850 cc float and filter lids) -Lid has shut off valve to protects from overfill -Portable, easy carry -Light Weight - Inline Hydrophobic Filter -Vacuum gauge	-Reusable and disposable containers (800cc/1200cc) -Lid has a float shut off valve that protects from overfill -Portable, easy carry -Light Weight -Filters (inline, Bacterial or Hydrophobic) -Vacuum gauge	Similar
Safety Features	-Overflow protection	-Overflow Protection	Same
Accessories	-Suction Tubing - Disposable canisters -Intermediate Tubing - Inline Hydrophobic Filter -Suction Catheter	-Suction tubing -Inline filter (Bacterial or Hydrophobic) -Disposable or reusable Canister (800/1200cc) -800cc Inlet Adaptor Kit - Carry Bag -AC Power Cord	Similar
Device Dimensions	(L) 293 x (W) 192 x (H) 245 mm	With Disposable bottle- 218x 160x 204mm With Reusable bottle- 186x160x 187mm	Different
Prescription vs. OTC	Rx	Rx	Same
Sterile vs. Non-Sterile	Non- Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Aspirator is reusable accessories – single patient use	Aspirator is reusable accessories- single patient use, canister is also offer reusable	Same
Power	AC Only Model	AC only model (PM66AC)	Same
Voltage	AC 120V, 60Hz	AC 100-240V, 50-60Hz	Similar
Input Current	1.5 Amps	0.60-0.25 Amps	Different
Vacuum Range	16.20~ 84.68kPa	0~94kPa	Different
Canister	850cc Disposable	800cc and 1200cc Disposable and reusable	Similar (for disposable canister)
Electrical Requirements	Class II, Type BF	Class II, Type BF	Same

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Equipment Type	High Vacuum/Low Flow	High Vacuum/ High Flow	Different
Working Mode	<30 continuous minutes	15 minutes on, 15 minutes off within a 2 hour cycle	Different
Operating Temperature	41° ~ 104° F (5° ~ 40°C)	0° ~ 122° F (-18° ~ 50°C)	Different
Operating Humidity	≤93% Relative Humidity	95% Noncondensing	Different

Summary of Non-Clinical Testing

Non-clinical verification of the Medline Vacu-line Suction Aspirator has been conducted to evaluate its safety, performance and functionality. The results of these tests have demonstrated the overall safety of the proposed device and its effectiveness in accordance with relevant test methods, and ultimately support a substantial equivalence determination. Full performance testing reports for can be found in Appendix D.

Performance Testing (Bench)

The following testing was conducted on the Medline Vacu-line Suction Aspirator:

Air Flow Rate
The aspirator displayed an average airflow rate of 24± 1.1 L/min

Pressure Test
The aspirator displayed an minimum vacuum range of 21.15 ± 4.86 kPa and a maximum vacuum range of 82.84 ± 1.84 kPa

Working Current
The aspirator displayed an average working current of 1.2 ± 0.0 Amps

Noise Level
The aspirator displayed a noise level of 66.81 ± 1.37 dB in an open atmosphere and 68.42 ± 0.93 dB in a closed atmosphere

Other Testing

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Electromagnetic Compatibility & Electrical Safety

- IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2015 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance- Collateral Standards: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010, Medical Electrical Equipment Part 1-6: General requirements for safety- Collateral Standard: Usability
- EN ISO 10079-1:2015, Medical suction equipment — Part 1: Electrically powered suction equipment

Cleaning Validation

A Cleaning validation was conducted by cleaning the suction aspirator 150 times with Microkill+ alcohol based wipes, without affecting the performance or appearance of the device.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Vacu-line Suction Aspirator is as safe and as effective for their intended use as the predicate device, EasyGoVac K140179.