May 12, 2023

SOMAVAC Medical Solutions, Inc.
℅ Dawn Norman
Partner
MRC Global LLC
9085 E. Mineral Cir., Suite 110
Centennial, Colorado 80112

RE: K231063
Trade/Device Name: SOMAVAC® 100 Sustained Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 13, 2023
Received: April 14, 2023

Dear Ms. Norman:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.12 08:53:51 -04'00'

Mark Trumbore, 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)*
K231063

Device Name
SOMAVAC® 100

Indications for Use *(Describe)*
The SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100) is a portable battery powered vacuum source / waste container intended for the removal of surgical and bodily fluids from a closed wound following plastic surgery and other general surgery forming large flaps for hematoma and seroma prophylaxis. It is intended for use in homecare and healthcare 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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SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)
K231063
May 10, 2023

Company: SOMAVAC Medical Solutions, Inc.
3144 Stage Post Rd Suite 101
Bartlett, TN 38133

Primary Contact: Ms. Dawn N. Norman, MS
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SOMAVAC Medical Solutions, Inc.
Phone: 901-212-2198
phil.ryan@somavac.com

Trade Name: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)

Common Name: Pump, Portable, Aspiration (Manual Or Powered)

Classification: Class II

Regulation Number: 21 CFR 878.4780

Panel: General and Plastic Surgery

Product Code: BTA

Primary Predicate: SOMAVAC® 100 (K222856),
Manufacturer: SOMAVAC Medical Solutions, Inc.

Device Description:
The SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100) is a portable, battery-powered vacuum pump/waste container intended for the removal of surgical and bodily fluids from a closed wound following plastic surgery and other general surgery forming large flaps for hematoma and seroma prophylaxis. It is intended for homecare and healthcare environments. The SOMAVAC® 100 may be used for most instances a surgeon determines a closed suction drain device is applicable. The SOMAVAC® 100 is compatible with drains commonly used after surgeries and is intended to be used by a single patient. The SOMAVAC® 100 is to be installed by trained medical personnel. Post-installation (in patient setting or at home), the SOMAVAC® 100 is intended to be operated by patients or their caregivers.

Indications for Use:
The SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100) is a portable battery powered vacuum source / waste container intended for the removal of surgical and bodily fluids from a closed wound following plastic surgery and other general surgery forming large flaps for hematoma and seroma prophylaxis. It is intended for use in homecare and healthcare environments.

Substantial Equivalence:
The SOMAVAC® 100 uses the same fundamental technology as the predicate device. The indications for use of the subject device is identical to the predicate device. The additional sterilization method for the drain connector accessories for the SOMAVAC® 100 does not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and validation testing has demonstrated that no adverse effects have been introduced by these changes and that the device performs as intended.

From the results of nonclinical testing described, SOMAVAC Medical Solutions concludes that the SOMAVAC® 100 is substantially equivalent to the legally marketed predicate devices. The table below summarizes the key differences between the SOMAVAC® 100 and the predicate device.

	Subject SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	**Primary Predicate K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)**	**Assessment of Differences**
Regulatory status	Class II	Class II	Identical
Classification name	Pump, portable, aspiration.	Pump, portable, aspiration.	Identical
Regulation	878.4780	878.4780	Identical
Product Code	BTA	BTA	Identical

	Subject SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Primary Predicate K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Assessment of Differences
Vacuum pressure	-60 to -350 mmHg	-60 to -350 mmHg	Identical
Use setting	Home and health care environment	Home and health care environment	Identical
Indication for use	The SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100) is a portable battery powered vacuum source / waste container intended for the removal of surgical and bodily fluids from a closed wound following plastic surgery and other general surgery forming large flaps for hematoma and seroma prophylaxis. It is intended for use in homecare and healthcare environments.	The SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100) is a portable battery powered vacuum source / waste container intended for the removal of surgical and bodily fluids from a closed wound following plastic surgery and other general surgery forming large flaps for hematoma and seroma prophylaxis. It is intended for use in homecare and healthcare environments.	Identical
Waste Collection Capacity	50mL/drain 100 mL total (disposable waste collection units)	50mL/drain 100 mL total (disposable waste collection units)	Identical
Flow @ Max Vacuum	1.0 mL/min	1.0 mL/min	Identical
Electrical	3VDC 2xAA batteries (series connection)	3VDC 2xAA batteries (series connection)	Identical
Weight	300 gram w/batteries	300 gram w/batteries	Identical
Electrical Equipment Classification	Class II Type BF IP (22)	Class II Type BF IP (22)	Identical
Transport	Portable, wearable Delivered in a belt to be worn by the patient	Portable, wearable Delivered in a belt to be worn by the patient	Identical
Mode of operation	Non-continuous, intermittent, controlled by vacuum pressure and the amount of exudate collected	Non-continuous, intermittent, controlled by vacuum pressure and the amount of exudate collected	Identical

	Subject SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Primary Predicate K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Assessment of Differences
Accessories	• drain connectors, sterile via ethylene oxide or gamma radiation • waste collection units • belt • AA batteries	• drain connectors, sterile via gamma radiation • waste collection units • belt • AA batteries	Substantially Equivalent

Performance Testing:
The SOMAVAC® 100 continues to comply with voluntary standards for software, electrical safety, electromagnetic compatibility, and powered suction pumps which has not changed since the original clearance. The additional sterilization method for the drain connector accessories does not affect the substantial equivalence to the predicate device SOMAVAC® 100. Therefore, the previous functional performance testing for verification and validation is applicable to the subject device. and that previous is applicable.

In the predicate submission (SOMAVAC® 100, K222856), the drain connector accessories are provided sterile via gamma irradiation. A secondary sterilization method, ethylene oxide (EO), has been validated for the drain connector accessories per the following standards:

- ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation, and routine control of a sterilization process for medical devices
- ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

Packaging evaluations to confirm seal strength were conducted post sterilization to confirm the additional sterilization method, ethylene oxide, does not impact the packaging or shelf life:

Standard	Description	Results
ASTM F88/F88M (at T=0 & T=3 years)	Standard Test Method for Seal Strength of Flexible Barrier Materials	Pass
ASTM 1886 (at T=0 & T=3 years)	Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Pass

Conclusion:
The intended use and indications for use of the SOMAVAC® 100 subject device are identical to the predicate device. The additional sterilization method for the drain connector accessories of the SOMAVAC® 100 does not introduce a new intended use and does not raise new issues of safety and effectiveness. Verification and validation rationales have demonstrated that no adverse effects have been introduced by the ethylene oxide sterilization method and that the device continues to perform as intended.

From the results of nonclinical testing described, the SOMAVAC® 100 subject device is substantially equivalent to the predicate, SOMAVAC® 100 (K222856).