October 19, 2022

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

Re: K222856
Trade/Device Name: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: September 21, 2022
Received: September 21, 2022

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,

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)*
K222856

Device Name
SOMAVAC® 100 Sustained Vacuum System (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.

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K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)
October 17, 2022

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

Primary Contact: Ms. Dawn Norman, MS
Partner; MRC Global, LLC
9085 E. Mineral Circle
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Company/Secondary Contact: Mr. Phil Ryan
COO
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® Device (K180606),
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:
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 updates to SOMAVAC® 100 do 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 concludes that SOMAVAC® 100 is substantially equivalent to the legally marketed predicate devices. The table below summarizes the key differences between SOMAVAC® 100 and the predicate device.

	Subject K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	**Predicate K180606: SOMAVAC® Device**	**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
Vacuum pressure	-60 to -350 mmHg	-60 to -350 mmHg	Identical
Use setting	Home and health care environment	Home and health care environment	Identical

	Subject K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Predicate K180606: SOMAVAC® Device	Assessment of Differences
Indication for use	The SOMAVAC® 100 Sustained Vacuum System 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® Device 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 alkaline batteries (series connection)	Substantially Equivalent Alkaline or lithium-ion batteries are appropriate.
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 K222856: SOMAVAC® 100 Sustained Vacuum System (SOMAVAC® 100)	Predicate K180606: SOMAVAC® Device	Assessment of Differences
Accessories	• drain connectors, sterile • waste collection units • belt • AA batteries	• drain connectors, non-sterile • waste collection units • belt • AA batteries	Substantially Equivalent; The offering of sterile drain connectors does not affect the substantial equivalence between the predicate and subject device.

Performance Testing:
The SOMAVAC® 100 device complies with voluntary standards for electrical safety, electromagnetic compatibility, and powered suction pumps. The materials and mechanical properties have been evaluated to confirm the changes to the SOMAVAC® 100 device do not affect the substantial equivalence to the predicate device:

- The software change was developed and validated in accordance with FDA guidances: Deciding When to Submit a 510(k) for a Software Change to an Existing Device (issued October 25, 2017); General Principles of Software Validation (issued January 11, 2002); and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005). The IEC 62304:2006 Software Safety Class for this device remains Class "B".
- Verification of vacuum and flow measurements to confirm that the vacuum levels and flow of the pump continues to meet the specifications.
- Packaging evaluations peel strength, gross leaks, and burst strength were performed following gamma irradiation sterilization to confirm appropriate packaging of sterile accessories.

Conclusion:
The intended use and indications for use of the SOMAVAC® 100 subject device is identical to the predicate device. The updates to the SOMAVAC® 100 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 changes and that the device performs as intended.

From the results of nonclinical testing described, the SOMAVAC® 100 subject device is substantially equivalent to the predicate, SOMAVAC® Device (K180606).