

K231063 SOMAVAC® 100 Sustained Vacuum SystemMay 12, 2023
28 days to decisionK231063 · Product code: **BTA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Apr 14, 2023
Decision date	May 12, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Somavac Medical Solutions, Inc.
Location	Memphis, TN, US
Contact	Phil Ryan
510(k) history	3 submissions · 3 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231063/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026