

K251646 extriCARE® 1000 Negative Pressure Wound Therapy SystemOct 3, 2025
127 days to decisionK251646 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	May 29, 2025
Decision date	Oct 3, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alleva Medical Devices
Location	Brea, CA, US
Contact	Max Choi
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Addwin Consulting
Contact	Mona Advani

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251646/> 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 14, 2026