

K221223 extriCARE® 3000 Negative Wound Pressure Therapy SystemFeb 9, 2023
287 days to decisionK221223 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Apr 28, 2022
Decision date	Feb 9, 2023
Days to decision	287 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 Corporation
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/k221223/> 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 27, 2026