

**K213906 extriCARE 1000 Negative Pressure Wound Therapy System**Mar 8, 2023  
449 days to decisionK213906 · Product code: **OMP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k213906/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Dec 14, 2021
Decision date	Mar 8, 2023
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alleva Medical, Ltd.</b>
Location	Shek Mun, HK
Contact	Max Choi
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213906/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026