

K250708 NPsealApr 8, 2025
29 days to decisionK250708 · Product code: **OKO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Negative Pressure Wound Therapy Non-powered Suction Apparatus (OKO)
Date received	Mar 10, 2025
Decision date	Apr 8, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guard Medical, Inc.
Location	New York, NY, US
Contact	Machiel van der Leest
510(k) history	7 submissions · 7 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	AlvaMed, Inc.
Contact	Eric Bannon

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/k250708/> 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