

**K212971 NPseal**Feb 10, 2022  
146 days to decisionK212971 · Product code: **OKO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Non-powered Suction Apparatus (OKO)
Date received	Sep 17, 2021
Decision date	Feb 10, 2022
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guard Medical, Inc.</b>
Location	New York, NY, US
Contact	Machiel Van Der Leest
510(k) history	7 submissions · 7 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>AlvaMed, Inc.</b>
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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212971/> 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 26, 2026