

**K240244 NPseal (Small, Medium, Large)**Feb 29, 2024  
30 days to decisionK240244 · Product code: **OKO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k240244/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Negative Pressure Wound Therapy Non-powered Suction Apparatus (OKO)
Date received	Jan 30, 2024
Decision date	Feb 29, 2024
Days to decision	30 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)

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