

**K241522 NPseal (20 and 25)**Aug 15, 2024  
78 days to decisionK241522 · Product code: **OKO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241522/>**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         | May 29, 2024  |
| Decision date         | Aug 15, 2024  |
| Days to decision      | 78 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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241522/> 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 13, 2026