

**K161948 Avance Gauze Dressing Kits**Nov 3, 2016  
111 days to decisionK161948 · Product code: **OMP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k161948/>**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         | Jul 15, 2016   |
| Decision date         | Nov 3, 2016  |
| Days to decision      | 111 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Molnlycke Health Care Us, LLC</b>    |
| Location       | Norcross, GA, US                        |
| Contact        | MEGAN BEVILL                            |
| 510(k) history | 27 submissions · 27 cleared · 2006-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161948/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 2, 2026