

**K181659 Avologi ENEO**Jul 26, 2018  
31 days to decisionK181659 · Product code: **OHS** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k181659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Jun 25, 2018
Decision date	Jul 26, 2018
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Premier North America, Inc.</b>
Location	Fort Lauderdale, FL, US
Contact	Yaniv Applicant
510(k) history	6 submissions · 6 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181659/> 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 May 25, 2026