

**K220735 Avologi Gel Primer (Model: Av25)**Sep 15, 2023  
550 days to decisionK220735 · Product code: **GYB** · Neurology  
Source: <https://www.510kdatabase.net/k220735/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Electroconductive (GYB)
Date received	Mar 14, 2022
Decision date	Sep 15, 2023
Days to decision	550 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	Ellis Tamari
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/k220735/> 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