

**K234091 Maverick Diagnostic System TC1000**Jul 22, 2024  
209 days to decisionK234091 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k234091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Dec 26, 2023
Decision date	Jul 22, 2024
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement
Other names	Maverick Test Panel A0.B0

**APPLICANT**

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Company	<b>Genalyte, Inc.</b>
Location	San Diego, CA, US
Contact	Sasi Mudumba
510(k) history	2 submissions · 2 cleared · 2019-2024

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234091/> 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 14, 2026