

**K191085 Maverick RNP Assay and Maverick Diagnostic System**Oct 25, 2019  
184 days to decisionK191085 · Product code: **LKO** · Immunology  
Source: <https://www.510kdatabase.net/k191085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Apr 24, 2019
Decision date	Oct 25, 2019
Days to decision	184 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Genalyte, Inc.</b>
Location	San Diego, CA, US
Contact	Rick Hockett
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/k191085/> 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 26, 2026