

**K243922 Revogene**Mar 20, 2025  
90 days to decisionK243922 · Product code: **OOI** · Microbiology  
Source: <https://www.510kdatabase.net/k243922/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Dec 20, 2024
Decision date	Mar 20, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meridian Bioscience, Inc.</b>
Location	Cincinnati, OH, US
Contact	Whitney Rooker
510(k) history	38 submissions · 37 cleared · 2003-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243922/> 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