

K222779 RevogeneJan 26, 2023
134 days to decisionK222779 · Product code: **OOI** · Microbiology
Source: <https://www.510kdatabase.net/k222779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Sep 14, 2022
Decision date	Jan 26, 2023
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Bioscience, Inc.
Location	Cincinnati, OH, US
Contact	Jack Rogers
510(k) history	38 submissions · 37 cleared · 2003-2025

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