

K220480 RevogeneJul 11, 2022
143 days to decisionK220480 · Product code: **OOI** · Microbiology
Source: <https://www.510kdatabase.net/k220480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Real Time Nucleic Acid Amplification System (OOI)
Date received	Feb 18, 2022
Decision date	Jul 11, 2022
Days to decision	143 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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