FDA 510(k) Premarket Notification

K220480 Revogene

CLEARED

Jul 11, 2022
143 days to decision

K220480 · 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