FDA 510(k) Premarket Notification

CLEARED

K212778 Alinity m EBV AMP Kit (List No. 09N43-095), Alinity m EBV CTRL Kit (List No. 09N43-085), Alinity m EBV CAL Kit (List No. 09N43-075)

Jul 15, 2022
317 days to decision

K212778 · Product code: **QLX** · Microbiology
Source: https://www.510kdatabase.net/k212778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Test For The Quantitation Of Epstein-barr Virus (ebv) Dna (QLX)
Date received	Sep 1, 2021
Decision date	Jul 15, 2022
Days to decision	317 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Molecular, Inc.**
Location	Des Plaines, IL, US
Contact	Gina Sammarco
510(k) history	17 submissions · 16 cleared · 2008-2025