FDA 510(k) Premarket Notification

K113323 ARTUS INFL A/B RG RT-PCR KIT

CLEARED

Feb 6, 2012
88 days to decision

K113323 · Product code: **OCC** · Microbiology
Source: https://www.510kdatabase.net/k113323/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Nov 10, 2011
Decision date	Feb 6, 2012
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**QIAGEN GmbH**
Location	Hilden, DE
Contact	KIM DAVIS
510(k) history	13 submissions · 13 cleared · 2012-2026