FDA 510(k) Premarket Notification

K991633 QUICKVUE INFLUENZA A/B TEST

CLEARED

Sep 24, 1999
135 days to decision

K991633 · Product code: **PSZ** · Microbiology
Source: https://www.510kdatabase.net/k991633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	May 12, 1999
Decision date	Sep 24, 1999
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Quidel Corp.**
Location	Washington, DC, US
Contact	MARY DE ARMOND
510(k) history	93 submissions · 93 cleared · 1983-2013