FDA 510(k) Premarket Notification

K061008 QUICKVUE RSV (20 TEST KIT), MODEL 20193

CLEARED

Sep 8, 2006
149 days to decision

K061008 · Product code: **MCE** · Microbiology
Source: https://www.510kdatabase.net/k061008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus - Elisa (MCE)
Date received	Apr 12, 2006
Decision date	Sep 8, 2006
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary
Other names	(2 TEST KIT), MODEL 20199

APPLICANT

Company	**Quidel Corp.**
Location	Washington, DC, US
Contact	JOHN D TAMERIUS
510(k) history	93 submissions · 93 cleared · 1983-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k061008/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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