

**K896926 DIRECTIGEN 1-2-3 INFECTIOUS MONONUCLEOSIS
CONTROLS**Jan 26, 1990
46 days to decisionK896926 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k896926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	Dec 11, 1989
Decision date	Jan 26, 1990
Days to decision	46 days
Third-party review	No

APPLICANT

Company	Quidel Corp.
Location	Washington, DC, US
Contact	Robin Weiner
510(k) history	93 submissions · 93 cleared · 1983-2013

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