

K893737 DIRECTIGEN 1-2-3 INFECTIOUS MONONUCLEOSIS TESTJun 16, 1989
30 days to decisionK893737 · Product code: **KTN** · Immunology
Source: <https://www.510kdatabase.net/k893737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Infectious Mononucleosis (KTN)
Date received	May 17, 1989
Decision date	Jun 16, 1989
Days to decision	30 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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