

K974108 SERUM HCG CONTROL SET (NEGATIVE, LOW POSITIVE AND HIGH POSITIVE)Nov 26, 1997
26 days to decisionK974108 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k974108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Oct 31, 1997
Decision date	Nov 26, 1997
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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