

**K121237 BETA HCG CONTROL LEVEL 1 BETA HCG CONTROL
LEVEL 2 BETA HCG CONTROL LEVEL 3 BETA HCG
CALIBRATION VERIFICATION CONTROLS LE**

May 18, 2012
24 days to decision

K121237 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k121237/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Apr 24, 2012
Decision date	May 18, 2012
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cliniqa Corporation
Location	Fallbrook, CA, US
Contact	DAWN GAST
510(k) history	36 submissions · 36 cleared · 2001-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k121237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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