

**K110061 CVM, UNCONJUGATED ESTRIOL (UE3) CALIBRATION
VERIFICATION MATERIAL**Sep 21, 2011
254 days to decisionK110061 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k110061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 10, 2011
Decision date	Sep 21, 2011
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	Ernest Joseph
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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