

K102904 ENHANCED ESTRADIOL (EE2) MASTER CURVE MATERIALNov 23, 2010
53 days to decisionK102904 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k102904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Oct 1, 2010
Decision date	Nov 23, 2010
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102904/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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