

K150606 Emit II Plus Buprenorphine Assay, Emit II Plus Specialty Drug Calibrator/Control Level 1, Level 2 Level 3, Level 4, Emit II Plus Specialty Drug Control Negative, Emit II Plus Specialty Drug Control PositiveOct 23, 2015
227 days to decisionK150606 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k150606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 10, 2015
Decision date	Oct 23, 2015
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	FRANCES A. DILLON
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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