

K102779 EMIT II PLUS6-ACETYLMORPHINE ASSAYMar 18, 2011
175 days to decisionK102779 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k102779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Sep 24, 2010
Decision date	Mar 18, 2011
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary
Other names	EMIT II PLUS 6-AM/ ECSTASY CALIBRATOR/ CONTROL LEVEL 1; EMIT II PLUS 6-AM / ECTASY C

APPLICANT

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

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