

K103836 ENZYME II CALIBRATORFeb 16, 2011
48 days to decisionK103836 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k103836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 30, 2010
Decision date	Feb 16, 2011
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k103836/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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