

**K013850 STANDARD A, STANDARD B, STANDARD C, CAL,
SLOPE**

Dec 21, 2001
31 days to decision

K013850 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k013850/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 20, 2001
Decision date	Dec 21, 2001
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diamond Diagnostics, Inc.
Location	Holliston, MA, US
Contact	LINDA M STUNDTNER
510(k) history	26 submissions · 26 cleared · 2001-2020

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Device record: <https://www.510kdatabase.net/k013850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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