

**K133751 DIAMOND DIAGNOSTICS ISE SERUM STANDARDS,
DIAMOND DIAGNOSTICS ISE URINE STANDARDS**

Aug 8, 2014
242 days to decision

K133751 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k133751/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 9, 2013
Decision date	Aug 8, 2014
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k133751/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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