FDA 510(k) Premarket Notification

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

CLEARED

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