

**K093357 DIAMOND MEDICA ISE MODULE CALIBRANT A  
MODEL ME-6370D, DIAMOND MEDICA ISE MODULE  
CALIBRANT B, MODEL ME-5410D**Jun 24, 2010  
239 days to decisionK093357 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k093357/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Oct 28, 2009
Decision date	Jun 24, 2010
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093357/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026