

K130628 PATHFAST CK-MB-II CALIBRATORSOct 4, 2013
210 days to decisionK130628 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k130628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Mar 8, 2013
Decision date	Oct 4, 2013
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mitsubishi Chemical Medience Corporation
Location	Bethesda, MD, US
Contact	Judi Smith
510(k) history	2 submissions · 2 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130628/> Data sourced from FDA 510(k) public records (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. - Generated June 7, 2026