

K102638 DIAZYME HOMOCYSTEINE ASSAY BUFFER BASED CALIBRATORSNov 30, 2010
77 days to decisionK102638 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k102638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 14, 2010
Decision date	Nov 30, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

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