

K121053 DIAZYME HOMOCYSTEINE POC TEST KITJul 31, 2012
116 days to decisionK121053 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k121053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Apr 6, 2012
Decision date	Jul 31, 2012
Days to decision	116 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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