

**K071971 DIAZYME HOMOCYSTEINE 2 REAGENT ENZYMATIC ASSAY KIT, AND CALIBRATORS, MODEL(S) DZXXXA, DZXXA-CAL**Sep 17, 2007  
62 days to decisionK071971 · Product code: **LPS** · Chemistry  
Source: <https://www.510kdatabase.net/k071971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Jul 17, 2007
Decision date	Sep 17, 2007
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diazyme Laboratories</b>
Location	Irvine, CA, US
Contact	CHARLES YU
510(k) history	41 submissions · 41 cleared · 2003-2018

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