

**K061296 DIAZYME HOMOCYSTEINE ENZYMATIC ASSAY KIT
FOR COBAS INTEGRA AND HOMOCYSTEINE CALIBRATOR**Jun 13, 2006
35 days to decisionK061296 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k061296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	May 9, 2006
Decision date	Jun 13, 2006
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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