

K121533 ST AIA-PACK HOMOCYSTEINEJun 15, 2012
22 days to decisionK121533 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k121533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	May 24, 2012
Decision date	Jun 15, 2012
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary
Other names	ST AIA-PACK HOMOCYSTEINE CALIBRATOR SET; AIA-PACK HOMOCYSTEINE CONTROL SET

APPLICANT

Company	Tosoh Bioscience, Inc.
Location	Grove City, OH, US
Contact	ROBERT WICK
510(k) history	20 submissions · 20 cleared · 2007-2025

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