

**K093960 ST AIA-PACK CYSTATIN C, MODEL 025217**Sep 14, 2010  
265 days to decisionK093960 · Product code: **NDY** · Chemistry  
Source: <https://www.510kdatabase.net/k093960/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Dec 23, 2009
Decision date	Sep 14, 2010
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tosoh Bioscience, Inc.</b>
Location	Grove City, OH, US
Contact	JUDITH K OGDEN
510(k) history	20 submissions · 20 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093960/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026