

**K080662 GENZYME CYSTATIN C REAGENT ANF GENZYME  
CYSTATIN C CALIBRATOR**May 15, 2008  
66 days to decisionK080662 · Product code: **NDY** · Chemistry  
Source: <https://www.510kdatabase.net/k080662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Mar 10, 2008
Decision date	May 15, 2008
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corporation</b>
Location	Cambridge, MA, US
Contact	ERIC LAWSON
510(k) history	6 submissions · 6 cleared · 2005-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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