

**K111664 DIAZYME CYSTATIN C POC TEST KIT**Mar 30, 2012  
290 days to decisionK111664 · Product code: **NDY** · Chemistry  
Source: <https://www.510kdatabase.net/k111664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Jun 14, 2011
Decision date	Mar 30, 2012
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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