

K093680 DIAZYME CYSTATIN C ASSAYApr 8, 2010
132 days to decisionK093680 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k093680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Nov 27, 2009
Decision date	Apr 8, 2010
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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