

**K072270 DIAZYME CYSTATIN C: ASSAY KIT (DZ133A-K), CALIBRATOR (DZ133A-CAL), CONTROLS (DZ133A-CON)**

Feb 1, 2008  
170 days to decision

K072270 · Product code: **NDY** · Chemistry  
Source: <https://www.510kdatabase.net/k072270/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Aug 15, 2007
Decision date	Feb 1, 2008
Days to decision	170 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k072270/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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