

**K071388 GENTIAN CYSTATIN C IMMUNOASSAY**Nov 6, 2007  
172 days to decisionK071388 · Product code: **NDY** · Chemistry  
Source: <https://www.510kdatabase.net/k071388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	May 18, 2007
Decision date	Nov 6, 2007
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gentian AS</b>
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	2 submissions · 2 cleared · 2007-2008

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