

K081875 GENTIAN CYSTATIN C IMMUNOASSAYAug 20, 2008
49 days to decisionK081875 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k081875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Cystatin C (NDY)
Date received	Jul 2, 2008
Decision date	Aug 20, 2008
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gentian AS
Location	San Diego, CA, US
Contact	ERIC S GRUFF
510(k) history	2 submissions · 2 cleared · 2007-2008

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