

K093137 K-ASSAY CYSTATIN C REAGENT, CALIBRATOR AND CONTROLSep 28, 2010
358 days to decisionK093137 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k093137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Oct 5, 2009
Decision date	Sep 28, 2010
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kamiya Biomedical Co.
Location	Thousand Oaks, CA, US
Contact	SHAWN KAPLAN
510(k) history	43 submissions · 43 cleared · 1991-2010

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