

K083906 ADVIA CHEMISTRY CYSTATIN C REAGENT, ADVIA CHEMISTRY CYSTATIN C CALIBRATOR, MODELS P/N 04851534, P/N 10376487

Mar 11, 2009
71 days to decision

K083906 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k083906/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Dec 30, 2008
Decision date	Mar 11, 2009
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	KIRA GORDON
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083906/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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