

**K083386 ADVIA CHEMISTRY CALCIUM_2 (CA_2) METHOD,
MODELS P/M 02189699 (40 ML FILL), P/N 02189915 (70 ML FILL)**

Apr 2, 2009
136 days to decision

K083386 · Product code: CJY · Chemistry
Source: <https://www.510kdatabase.net/k083386/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Azo Dye, Calcium (CJY)
Date received	Nov 17, 2008
Decision date	Apr 2, 2009
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083386/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 28, 2026