

**K050077 SPOTCHEM II CALCIUM, MAGNESIUM, AND BLOOD
UREA NITROGEN TESTS**Feb 15, 2005
34 days to decisionK050077 · Product code: **CIC** · Chemistry
Source: <https://www.510kdatabase.net/k050077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cresolphthalein Complexone, Calcium (CIC)
Date received	Jan 12, 2005
Decision date	Feb 15, 2005
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Arkray, Inc.
Location	Beverly, MA, US
Contact	HELEN LANDICHO
510(k) history	18 submissions · 18 cleared · 2002-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050077/>. 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 26, 2026