

**K053401 SPOTCHEM II CHEMISTRY BASIC 1 AND CHEMISTRY  
BASIC 2 TESTS**Mar 24, 2006  
108 days to decisionK053401 · Product code: **CIC** · Chemistry  
Source: <https://www.510kdatabase.net/k053401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cresolphthalein Complexone, Calcium (CIC)
Date received	Dec 6, 2005
Decision date	Mar 24, 2006
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053401/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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