

**K051432 SPOTCHEM II TOTAL BILIRUBIN, TOTAL PROTEIN
AND ALBUMIN TESTS**Jun 17, 2005
16 days to decisionK051432 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k051432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 1, 2005
Decision date	Jun 17, 2005
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

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/k051432/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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