

K050652 SPOTCHEM II CREATININE, AMYLASE & ALP TESTSApr 6, 2005
23 days to decisionK050652 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k050652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Mar 14, 2005
Decision date	Apr 6, 2005
Days to decision	23 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

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