

K050790 SPOTCHEM II LDH TESTJun 6, 2005
70 days to decisionK050790 · Product code: **CFH** · Chemistry
Source: <https://www.510kdatabase.net/k050790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tetrazolium Int Dye-diaphorase, Lactate Dehydrogenase (CFH)
Date received	Mar 28, 2005
Decision date	Jun 6, 2005
Days to decision	70 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

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