

K030553 ARKIT HBA1CSep 2, 2003
193 days to decisionK030553 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k030553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 21, 2003
Decision date	Sep 2, 2003
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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