

K963844 HYDRAGEL 15 HB A1C KITApr 22, 1997
209 days to decisionK963844 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k963844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 25, 1996
Decision date	Apr 22, 1997
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Morax
Location	Chelsea, MI, US
Contact	BOREK JANIK
510(k) history	12 submissions · 12 cleared · 1996-2003

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