

**K983253 PRECISION A1C HOME HBA1C SAMPLE COLLECTION
KIT**Nov 20, 1998
65 days to decisionK983253 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k983253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 16, 1998
Decision date	Nov 20, 1998
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medisense, Inc.
Location	Cambridge, MA, US
Contact	DENISE HALEY
510(k) history	15 submissions · 15 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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