

**K100547 ELITECH CLINICAL SYSTEMS HBA1C REAGENT,
ELITECH CLINICAL SYSTEM HBA1C CALIBRATOR SET,
ELITECH CLINICAL**May 19, 2011
448 days to decisionK100547 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k100547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 25, 2010
Decision date	May 19, 2011
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seppim S.A.S.
Location	Bothell, WA, US
Contact	DEBRA K HUTSON
510(k) history	6 submissions · 6 cleared · 2010-2011

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