

**K100525 ELITECH CLINICAL SYSTEMS GLUCOSE PAP SL
ELITECH CLINICAL SYSTEMS ELICAL 2, ELITECH CLINICAL
SYSTEMS ELITROL 1 AND 2**Dec 15, 2010
294 days to decisionK100525 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k100525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 24, 2010
Decision date	Dec 15, 2010
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100525/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 16, 2026