

**K103747 ELITECH CLINCAL SYSTEMS CHOLESTEROL HDL SL
2G, HDL 2G CALIBRATOR, LDL SL 2G, LDL 2G CALIBRATOR,
ELITROL II & ELITECH SYS**Aug 31, 2011
251 days to decisionK103747 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k103747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Dec 23, 2010
Decision date	Aug 31, 2011
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elitechgroup Seppim S.A.S.
Location	Bothell, WA, US
Contact	DEBRA K HUTSON
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103747/>; 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 18, 2026