

**K063209 HBA1C**Mar 21, 2007  
149 days to decisionK063209 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k063209/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 23, 2006
Decision date	Mar 21, 2007
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement
Other names	CALIBRATOR; CONTROL NORMAL, CONTROL ABNORMAL

**APPLICANT**

---

Company	<b>Thermo Electron OY</b>
Location	Vantaa, FI
Contact	PAIVI SORMUNEN
510(k) history	9 submissions · 9 cleared · 2006-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063209/> 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 26, 2026