

**K063131 CARBAMAZEPINE, VALPROIC ACID, TDM
CALIBRATION SET B AND ABTROL, NORTROL CONTROLS**Oct 5, 2007
357 days to decisionK063131 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k063131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Oct 13, 2006
Decision date	Oct 5, 2007
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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