

**K063145 PHENOBARBITAL, PHENYTOIN, TDM CALIBRATION
SET B AND ABTROL/NORTROL CONTROLS**Oct 17, 2007
366 days to decisionK063145 · Product code: **DIP** · Toxicology
Source: <https://www.510kdatabase.net/k063145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Oct 16, 2006
Decision date	Oct 17, 2007
Days to decision	366 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

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