FDA 510(k) Premarket Notification

K123271 ABBOTT PHENOBARBITAL ASSAY

CLEARED

Apr 26, 2013
189 days to decision

K123271 · Product code: **DLZ** · Chemistry
Source: https://www.510kdatabase.net/k123271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	Oct 19, 2012
Decision date	Apr 26, 2013
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Microgenics Corp.**
Location	Concord, CA, US
Contact	KAREN LEE
510(k) history	107 submissions · 106 cleared · 1985-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k123271/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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