

**K071644 ONLINE PHENOBARBITAL, MODEL 03016757190 &
03510620**Sep 12, 2007
89 days to decisionK071644 · Product code: **DLZ** · Toxicology
Source: <https://www.510kdatabase.net/k071644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	Jun 15, 2007
Decision date	Sep 12, 2007
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	DIMITRIS DEMIRTZOGLU
510(k) history	264 submissions · 263 cleared · 1999-2013

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