

K832097 PHENOBARTIAL ASSAY USE ON COBAS-BIOAug 11, 1983
43 days to decisionK832097 · Product code: **DLZ** · Chemistry
Source: <https://www.510kdatabase.net/k832097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	Jun 29, 1983
Decision date	Aug 11, 1983
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
510(k) history	448 submissions · 447 cleared · 1976-2001

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