

K942501 ACE CEDIA PHENOBARBITAL ASSAYOct 6, 1994
135 days to decisionK942501 · Product code: **DLZ** · Chemistry
Source: <https://www.510kdatabase.net/k942501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	May 24, 1994
Decision date	Oct 6, 1994
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Schiapparelli Biosystems, Inc.
Location	Fairfield, NJ, US
Contact	MARK A SPAIN, PH.D.
510(k) history	24 submissions · 24 cleared · 1993-1999

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