

K944085 ACE(TM) CEDIA(R) PHENYTOIN ASSAYDec 28, 1994
128 days to decisionK944085 · Product code: **DIP** · Chemistry
Source: <https://www.510kdatabase.net/k944085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Diphenylhydantoin (DIP)
Date received	Aug 22, 1994
Decision date	Dec 28, 1994
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026