

K973582 ACE PRIMIDONE REAGENT, AED CALIBRATORSNov 12, 1997
51 days to decisionK973582 · Product code: **DJD** · Toxicology
Source: <https://www.510kdatabase.net/k973582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Primidone (DJD)
Date received	Sep 22, 1997
Decision date	Nov 12, 1997
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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