

**K950028 PRIMIDONE FPIA REAGENT SET AND CALIBRATORS**Mar 21, 1995  
76 days to decisionK950028 · Product code: LFT · Toxicology  
Source: <https://www.510kdatabase.net/k950028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Primidone (LFT)
Date received	Jan 4, 1995
Decision date	Mar 21, 1995
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	HOYLE D HILL
510(k) history	164 submissions · 164 cleared · 1984-2002

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