

K901537 MODIFIED OPUS PHENOBARBITAL TEST SYSTEMJun 12, 1990
71 days to decisionK901537 · Product code: **LET** · Toxicology
Source: <https://www.510kdatabase.net/k901537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Phenobarbital (LET)
Date received	Apr 2, 1990
Decision date	Jun 12, 1990
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Pb Diagnostic Systems, Inc.
Location	Westwood, MA, US
Contact	LORI BARANAUSKAS
510(k) history	35 submissions · 35 cleared · 1988-1994

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