

K935229 OPUS DIGITOXINDec 22, 1993
51 days to decisionK935229 · Product code: **DPG** · Toxicology
Source: <https://www.510kdatabase.net/k935229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Digitoxin (125-i), Rabbit Antibody, Coated Tube Sep. (DPG)
Date received	Nov 1, 1993
Decision date	Dec 22, 1993
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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