

K911834 OPUS(R) ROZOAug 12, 1991
109 days to decisionK911834 · Product code: **LGD** · Immunology
Source: <https://www.510kdatabase.net/k911834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Apr 25, 1991
Decision date	Aug 12, 1991
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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