

K911940 OPUS(R) TOBRAMYCINJul 1, 1991
61 days to decisionK911940 · Product code: **LCR** · Toxicology
Source: <https://www.510kdatabase.net/k911940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Tobramycin (LCR)
Date received	May 1, 1991
Decision date	Jul 1, 1991
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

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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