

K894159 OPUS IMMUNOASSAY SYSTEMAug 3, 1989
50 days to decisionK894159 · Product code: **KHO** · Toxicology
Source: <https://www.510kdatabase.net/k894159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometer, For Clinical Use (KHO)
Date received	Jun 14, 1989
Decision date	Aug 3, 1989
Days to decision	50 days
Third-party review	No

APPLICANT

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

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