

K925703 OPUS SEROLOGY CONTROLSApr 8, 1993
147 days to decisionK925703 · Product code: **MJX** · Microbiology
Source: <https://www.510kdatabase.net/k925703/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Serological, Positive Control (MJX)
Date received	Nov 12, 1992
Decision date	Apr 8, 1993
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pb Diagnostics, Inc.
Location	Westwood, MA, US
Contact	M JOHANSEN
510(k) history	4 submissions · 4 cleared · 1991-1993

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