

**K934137 OPUS(R) SEROLOGY CONTROLS, MODIFICATION**Mar 7, 1994  
194 days to decisionK934137 · Product code: **MJX** · Microbiology  
Source: <https://www.510kdatabase.net/k934137/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Serological, Positive Control (MJX)
Date received	Aug 25, 1993
Decision date	Mar 7, 1994
Days to decision	194 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934137/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026