

**K924957 OPUS(R) VANCOMYCIN**Dec 11, 1992  
72 days to decisionK924957 · Product code: **LEH** · Toxicology  
Source: <https://www.510kdatabase.net/k924957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Sep 30, 1992
Decision date	Dec 11, 1992
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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