

K932279 OPUS(R) TOTAL B-HCG TEST SYSTEMJul 8, 1993
57 days to decisionK932279 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k932279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 12, 1993
Decision date	Jul 8, 1993
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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