

K901935 OPUS (TM) HCGJun 26, 1990
57 days to decisionK901935 · Product code: **JHI** · Toxicology
Source: <https://www.510kdatabase.net/k901935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 30, 1990
Decision date	Jun 26, 1990
Days to decision	57 days
Third-party review	No

APPLICANT

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

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