

K933675 OPUS TOTAL CKSep 8, 1993
42 days to decisionK933675 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k933675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jul 28, 1993
Decision date	Sep 8, 1993
Days to decision	42 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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