

K915850 OPUS MYOGLOBIN TEST SYSTEMMar 17, 1992
82 days to decisionK915850 · Product code: **DDR** · Immunology
Source: <https://www.510kdatabase.net/k915850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Dec 26, 1991
Decision date	Mar 17, 1992
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

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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