

K915838 OPUS FERRITIN TEST SYSTEMMar 18, 1992
85 days to decisionK915838 · Product code: **DGE** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igd, Rhodamine, Antigen, Antiserum, Control (DGE)
Date received	Dec 24, 1991
Decision date	Mar 18, 1992
Days to decision	85 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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