FDA 510(k) Premarket Notification

K915870 OPUS RUBELLA TEST SYSTEM

CLEARED

Mar 23, 1992
83 days to decision

K915870 · Product code: **LFX** · Pathology
Source: https://www.510kdatabase.net/k915870/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Dec 31, 1991
Decision date	Mar 23, 1992
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pb Diagnostics, Inc.**
Location	Westwood, MA, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	4 submissions · 4 cleared · 1991-1993