

K970877 IMMULITE CEASep 22, 1997
196 days to decisionK970877 · Product code: **DHX** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Mar 10, 1997
Decision date	Sep 22, 1997
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Products Corp.
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

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