

K924857 AIA-PACK CEA CALIBRATION VERIFICATION TEST SETMar 18, 1993
171 days to decisionK924857 · Product code: **DHX** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Sep 28, 1992
Decision date	Mar 18, 1993
Days to decision	171 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tosoh Medics, Inc.
Location	Washington, DC, US
Contact	RICHARD M CROMPTON
510(k) history	41 submissions · 41 cleared · 1990-2002

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