

K973244 ACTIVE PSA IRMA (DSL-9700)Aug 3, 1998
339 days to decisionK973244 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k973244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Aug 29, 1997
Decision date	Aug 3, 1998
Days to decision	339 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Systems Laboratories, Inc.
Location	Mchenry, IL, US
Contact	JOHN CLASS
510(k) history	94 submissions · 94 cleared · 1981-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973244/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026