

K002121 TOTAL PSA MICROTITER ELISAAug 30, 2000
48 days to decisionK002121 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k002121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jul 13, 2000
Decision date	Aug 30, 2000
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oncogene Science, Inc.
Location	Cambridge, MA, US
Contact	SHERYL BROWN-SHIMER
510(k) history	3 submissions · 3 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002121/> 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