

**K002313 COMPLEXED PSA MICROTITER ELISA**Aug 30, 2000  
30 days to decisionK002313 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k002313/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jul 31, 2000
Decision date	Aug 30, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002313/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026