

**K964020 AXSYM CA 125**Nov 4, 1997  
393 days to decisionK964020 · Product code: LTK · Immunology  
Source: <https://www.510kdatabase.net/k964020/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Oct 7, 1996
Decision date	Nov 4, 1997
Days to decision	393 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	JOY C SONSALLA
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

---