

**K823569 ABBOTT LABORATORIES STREP A EIA**Mar 1, 1983  
88 days to decisionK823569 · Product code: **GTZ** · Chemistry  
Source: <https://www.510kdatabase.net/k823569/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Dec 3, 1982
Decision date	Mar 1, 1983
Days to decision	88 days
Third-party review	No

**APPLICANT**

---

Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
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...

---