

K853978 TDX AMYLASEOct 15, 1985
19 days to decisionK853978 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k853978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromcresol Green Dye-binding, Albumin (CIX)
Date received	Sep 26, 1985
Decision date	Oct 15, 1985
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	MARY ZORC
Website	http://www.abbott.com
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...

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