FDA 510(k) Premarket Notification

CLEARED

K871240 ABBOTT A-GENT LD-1 ISOZYME REAGENT

May 13, 1987
47 days to decision

K871240 · Product code: **JGF** · Chemistry
Source: https://www.510kdatabase.net/k871240/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Lactate Dehydrogenase Isoenzymes (JGF)
Date received	Mar 27, 1987
Decision date	May 13, 1987
Days to decision	47 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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Device record: https://www.510kdatabase.net/k871240/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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