

**K821135 PREALBUMIN ENZYME IMMUNOASSAY**May 5, 1983  
380 days to decisionK821135 · Product code: **JZJ** · Hematology  
Source: <https://www.510kdatabase.net/k821135/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prealbumin, Antigen, Antiserum, Control (JZJ)
Date received	Apr 20, 1982
Decision date	May 5, 1983
Days to decision	380 days
Third-party review	No

**APPLICANT**

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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...

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