

K854944 TDX IMMUNOGLOBULIN M DIAGNOSTIC KITAug 27, 1986
260 days to decisionK854944 · Product code: **DAH** · Immunology
Source: <https://www.510kdatabase.net/k854944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gamma Globulin, Antigen, Antiserum, Control (DAH)
Date received	Dec 10, 1985
Decision date	Aug 27, 1986
Days to decision	260 days
Third-party review	No

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	KEITH MINTER
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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