FDA 510(k) Premarket Notification

K233932 Alinity i Toxo IgM

CLEARED

Aug 30, 2024
260 days to decision

K233932 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k233932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Dec 14, 2023
Decision date	Aug 30, 2024
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	Laura Fraczek
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k233932/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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