FDA 510(k) Premarket Notification

CLEARED

K230790 Alinity i Total B-hCG Reagent Kit, Alinity c Glucose Reagent Kit, Alinity c ICT Sample Diluent, Alinity ci-series

May 19, 2023
58 days to decision

K230790 · Product code: **DHA** · Chemistry
Source: https://www.510kdatabase.net/k230790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Mar 22, 2023
Decision date	May 19, 2023
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	Melissa Vaughan
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...