FDA 510(k) Premarket Notification

K842505 TDX REA IRON DIAGNOSTIC KIT

CLEARED

Aug 7, 1984
42 days to decision

K842505 · Product code: **CFM** · Chemistry
Source: https://www.510kdatabase.net/k842505/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bathophenanthroline, Colorimetry, Iron (non-heme) (CFM)
Date received	Jun 26, 1984
Decision date	Aug 7, 1984
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
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...