FDA 510(k) Premarket Notification

CLEARED

K163342 i-STAT Hematocrit test with i-STAT Alinity System

Aug 22, 2017
266 days to decision

K163342 · Product code: **JPI** · Hematology
Source: https://www.510kdatabase.net/k163342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Hematocrit Measuring (JPI)
Date received	Nov 29, 2016
Decision date	Aug 22, 2017
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	Tamara McCaw
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...