CLEARED

K991605 CELL-DYN 3500 SYSTEM WITH IMMATURE RETICULOCYTE FRACTION (IRF), CELL-DYN 3700 SYSTEM WITH IMMATURE RETICULOCYTE FRACTION

Jul 9, 1999
60 days to decision

K991605 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k991605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	May 10, 1999
Decision date	Jul 9, 1999
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	MICHELLE B ROEDING
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...