FDA 510(k) Premarket Notification

CLEARED

K190294 CELL-DYN Emerald 22 AL System

Mar 15, 2019
32 days to decision

K190294 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k190294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 11, 2019
Decision date	Mar 15, 2019
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	Madhu Gill
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...