FDA 510(k) Premarket Notification

K240402 Cito CBC System

CLEARED

Feb 3, 2025
360 days to decision

K240402 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k240402/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 9, 2024
Decision date	Feb 3, 2025
Days to decision	360 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cytochip, Inc.**
Location	Irvine, CA, US
Contact	Wendian Shi
510(k) history	1 submissions · 1 cleared · 2025-2025