

K243348 Athelas HomeFeb 6, 2026
466 days to decisionK243348 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k243348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 28, 2024
Decision date	Feb 6, 2026
Days to decision	466 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Athelas, Inc.
Location	Mountain View, CA, US
Contact	Tanay Tandon
510(k) history	3 submissions · 3 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243348/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026