

K240636 HemoScreen Hematology AnalyzerMay 2, 2024
57 days to decisionK240636 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k240636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 6, 2024
Decision date	May 2, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pixcell Medical Technologies
Location	Yokneam Ilit, IL
Contact	Yaara Ben-Yosef
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Zivd, LLC
Contact	Marcia L.Zucker

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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