

**K200828 Athelas Home**Mar 22, 2022  
722 days to decisionK200828 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k200828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 30, 2020
Decision date	Mar 22, 2022
Days to decision	722 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200828/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026