

**K232946 Yumizen H2500**May 21, 2024  
244 days to decisionK232946 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k232946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 20, 2023
Decision date	May 21, 2024
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>HORIBA ABX SAS</b>
Location	Montpellier Cedex 4, FR
Contact	Caroline Ferrer
510(k) history	17 submissions · 17 cleared · 2009-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232946/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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