

**K220031 Alinity h-series System**Aug 4, 2023  
576 days to decisionK220031 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k220031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jan 5, 2022
Decision date	Aug 4, 2023
Days to decision	576 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	Neha Vatsyayan
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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Device record: <https://www.510kdatabase.net/k220031/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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