

**K193124 UniceL DxH 800 Coulter Cellular Analysis System**Apr 16, 2020  
156 days to decisionK193124 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k193124/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 12, 2019
Decision date	Apr 16, 2020
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter</b>
Location	Miami, FL, US
Contact	Samy Puccio
Website	<a href="http://www.beckmancoulter.com/">http://www.beckmancoulter.com/</a>
510(k) history	8 submissions · 6 cleared · 2017-2024

Beckman Coulter is a global diagnostics company specializing in clinical laboratory instruments and assays. The company operates with a manufacturing facility in Miami, US, and provides comprehensive diagnostic solutions across immunology, hematology, chemistry, and microbiology disciplines. The company has received FDA 510(k) clearances from total submissions since 2017. Immunology devices, particularly flow cytometers and related panels, represent a dominant category in the company's cleared portfolio. The latest FDA 510(k) clearance was granted in 2024, reflecting cont...

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