

# K181599 Unicel DxH 800 Cellular Analysis System with Early Sepsis Indicator Application

Mar 18, 2019  
273 days to decisionK181599 · Product code: **QFS** · Microbiology  
Source: <https://www.510kdatabase.net/k181599/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monocyte Distribution Width Quantitative Measurement For Sepsis Risk Assessment (QFS)
Date received	Jun 18, 2018
Decision date	Mar 18, 2019
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter</b>
Location	Miami, FL, US
Contact	Radha Goolabsingh
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k181599/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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