

K232600 DxFLEX Flow CytometerNov 22, 2023
86 days to decisionK232600 · Product code: **OYE** · Immunology
Source: <https://www.510kdatabase.net/k232600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flow Cytometric Reagents And Accessories. (OYE)
Date received	Aug 28, 2023
Decision date	Nov 22, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ClearLLab 10C Panels

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Stephanie Harlacz
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

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