

K232904 Access OstaseApr 15, 2024
210 days to decisionK232904 · Product code: **CIN** · Chemistry
Source: <https://www.510kdatabase.net/k232904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic Separation, Alkaline Phosphatase Isoenzymes (CIN)
Date received	Sep 18, 2023
Decision date	Apr 15, 2024
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter
Location	Miami, FL, US
Contact	Kate Oelberg
Website	http://www.beckmancoulter.com/
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...