FDA 510(k) Premarket Notification

CLEARED

K183592 ClearLLab 10C Panels (B, T, M1, M2), Navios Flow Cytometer, Navios EX Flow Cytometer

Mar 21, 2019
90 days to decision

K183592 · Product code: **PWD** · Immunology
Source: https://www.510kdatabase.net/k183592/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flow Cytometric Test System For Hematopoietic Neoplasms (PWD)
Date received	Dec 21, 2018
Decision date	Mar 21, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter**
Location	Miami, FL, US
Contact	Anthony Dennis
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183592/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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