FDA 510(k) Premarket Notification

CLEARED

K182886 Cytomics FC 500 Series (MPL or MCL) Flow Cytometer

Sep 6, 2019
326 days to decision

K182886 · Product code: **GKZ** · Immunology
Source: https://www.510kdatabase.net/k182886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 15, 2018
Decision date	Sep 6, 2019
Days to decision	326 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter**
Location	Miami, FL, US
Contact	Samy Puccio
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/k182886/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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