

K162897 Navios EX Flow Cytometer, 6 Color/2 Laser, Navios EX Flow Cytometer, 8 Color/2 Laser, Navios EX Flow Cytometer, 10 Color/3 Laser

Jun 23, 2017
249 days to decision

K162897 · Product code: **OYE** · Immunology
Source: <https://www.510kdatabase.net/k162897/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flow Cytometric Reagents And Accessories. (OYE)
Date received	Oct 17, 2016
Decision date	Jun 23, 2017
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter
Location	Miami, FL, US
Contact	Suzana Otano
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...