CLEARED

K141932 AQUIOS CL FLOW CYTOMETER, AQUIOS TETRA-1 PANEL,AQUIOS TETRA-2+PANEL, AQUIOS IMMUNO-TROL, AQUIOS IMMUNO-TROL LOW, AQUIOS

Apr 10, 2015
268 days to decision

K141932 · Product code: **OYE** · Immunology
Source: https://www.510kdatabase.net/k141932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flow Cytometric Reagents And Accessories. (OYE)
Date received	Jul 16, 2014
Decision date	Apr 10, 2015
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	ANTHONY DENNIS
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,...