FDA 510(k) Premarket Notification

K121445 TETRACHROME REAGENTS AND TETRACXP SYSTEM

CLEARED

Jul 26, 2013
437 days to decision

K121445 · Product code: **OYE** · Hematology
Source: https://www.510kdatabase.net/k121445/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flow Cytometric Reagents And Accessories. (OYE)
Date received	May 15, 2012
Decision date	Jul 26, 2013
Days to decision	437 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	NANCY NADLER
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,...