FDA 510(k) Premarket Notification

CLEARED

K121214 ACCESS ACCUTNI+3 REAGENT AND ACCESS ACCUTN1+3 CALIBRATORS FOR USE ON THE ACCESS 2 IMMUNOASSAY SYSTEM

Jun 14, 2013
417 days to decision

K121214 · Product code: **MMI** · Chemistry
Source: https://www.510kdatabase.net/k121214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Apr 23, 2012
Decision date	Jun 14, 2013
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	KERRIE OETTER
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,...