

K121790 ACCESS ACCUTNI REAGENT, ACCESS ACCUTNI CALIBRATOR, UNICEL DXI 800 ACCESS IMMUNOASSAY SYSTEMSep 25, 2013
464 days to decisionK121790 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k121790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jun 18, 2012
Decision date	Sep 25, 2013
Days to decision	464 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,...