FDA 510(k) Premarket Notification

CLEARED

Sep 16, 2014
201 days to decision

K140496 Access Vitamin B12 Assay, Access Ferritin Assay, Access Folate Assay, Access HYPERsensitive hTSH Assay, Power Express Sample Processing System Generic Connection Module and Access Immunoassay System Reagents

K140496 · Product code: **CDD** · Chemistry
Source: https://www.510kdatabase.net/k140496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Feb 27, 2014
Decision date	Sep 16, 2014
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	NANETTE CANEPA
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,...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k140496/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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