FDA 510(k) Premarket Notification

CLEARED

K011465 SYNCHRON CX PRO CLINICAL SYSTEMS, MODEL CX4 PRO, CX5 PRO, CX7 PRO, CX9 PRO

Jun 8, 2001
25 days to decision

K011465 · Product code: **LDP** · Chemistry
Source: https://www.510kdatabase.net/k011465/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	May 14, 2001
Decision date	Jun 8, 2001
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	MARY B TANG
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,...