FDA 510(k) Premarket Notification

CLEARED

K140829 UNICEL DXC SYNCHRON SYSTEMS HEMOGLOBIN A1C3 (HBA1C3) REAGENT

Jul 14, 2014
104 days to decision

K140829 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k140829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 1, 2014
Decision date	Jul 14, 2014
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	ANNETTE HELLIE
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/k140829/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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