

K142985 UniCel DxC SYNCHRON System HDL Cholesterol reagent(HDL),Unicel DxC SYNCHRON System HDL CalibratorFeb 26, 2015
133 days to decisionK142985 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k142985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	Oct 16, 2014
Decision date	Feb 26, 2015
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Eimear Carr
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,...

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Device record: <https://www.510kdatabase.net/k142985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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