FDA 510(k) Premarket Notification

K120199 GLYCOSYLATED HEMOGLOBIN ASSAY

CLEARED

Oct 12, 2012
263 days to decision

K120199 · Product code: **LCP** · Chemistry
Source: https://www.510kdatabase.net/k120199/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jan 23, 2012
Decision date	Oct 12, 2012
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary
Other names	CLINICAL CHEMISTRY

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	BEVERLY HARDING
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,...