

**K103842 UNICEL DXC 600 SYNCHRON SYSTEM SOFTWARE
VERSION 5.0 AND UNICEL DXC 800 SYNCHRON SYSTEM
SOFTWARE VERSION 5.0**Apr 27, 2011
118 days to decisionK103842 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k103842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 30, 2010
Decision date	Apr 27, 2011
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	MARINE BOYAJIAN
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,...