

**K103373 SYNCHRON SYSTEMS CHOLINESTERASE (CHEX)
MODEL A53722**Feb 7, 2011
82 days to decisionK103373 · Product code: **DIH** · Toxicology
Source: <https://www.510kdatabase.net/k103373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Cholinesterase (DIH)
Date received	Nov 17, 2010
Decision date	Feb 7, 2011
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Yvette Lloyd
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/k103373/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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