

**K053090 DRI-STAT ENZYMATIC BILIRUBIN REAGENT,  
SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR**Dec 16, 2005  
44 days to decisionK053090 · Product code: JFM · Chemistry  
Source: <https://www.510kdatabase.net/k053090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Nov 2, 2005
Decision date	Dec 16, 2005
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	ERI HIRUMI
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
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,...