

K013076 SYNCHRON SYSTEMS VANCOMYCIN REAGENTDec 12, 2001
89 days to decisionK013076 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k013076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Sep 14, 2001
Decision date	Dec 12, 2001
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SYNCHRON SYSTEMS VANCOMYCIN CALIBRATOR

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	MARY BETH TANG
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,...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013076/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026