FDA 510(k) Premarket Notification

CLEARED

K021229 MYOGLOBIN AND MYOGLOBIN CALIBRATORS ON THE ACCESS IMMUNOASSAY SYSTEMS, MODEL 973243, 973244

Jun 28, 2002
71 days to decision

K021229 · Product code: **DDR** · Chemistry
Source: https://www.510kdatabase.net/k021229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Apr 18, 2002
Decision date	Jun 28, 2002
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	BRUCE BACKLUND
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,...