

**K030012 CK-MB AND CK-MB CALIBRATORS ON THE ACCESS
IMMUNOASSAY SYSTEMS, MODELS 386371 AND 386372**Jan 17, 2003
15 days to decisionK030012 · Product code: JHX · Chemistry
Source: <https://www.510kdatabase.net/k030012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Jan 2, 2003
Decision date	Jan 17, 2003
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	BRENT TABER
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,...