

K994439 ACCESS CK-MB ON THE ACCESS IMMUNOASSAY ANALYZER, MODELS 33300, 33305, 33309, 33306Jan 14, 2000
22 days to decisionK994439 · Product code: JHX · Chemistry
Source: <https://www.510kdatabase.net/k994439/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fluorometric Method, Cpk Or Isoenzymes (JHX) |
| Date received | Dec 23, 1999 |
| Decision date | Jan 14, 2000 |
| Days to decision | 22 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------------------------------------|
| Company | Beckman Coulter, Inc. |
| Location | Chaska, MN, US |
| Contact | MICHELE S GUST |
| 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,...