

K070144 INHIBIN A CALIBRATORS & CONTROLS ON THE ACCESS IMMUNOASSAY SYSTEMSFeb 1, 2007
16 days to decisionK070144 · Product code: JIT · Chemistry
Source: <https://www.510kdatabase.net/k070144/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Secondary (JIT) |
| Date received | Jan 16, 2007 |
| Decision date | Feb 1, 2007 |
| Days to decision | 16 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Beckman Coulter, Inc. |
| Location | Chaska, MN, US |
| Contact | TYLER J FOUTCH |
| 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,...