

K021572 SYNCHRON SYSTEMS C-REACTIVE PROTEIN (C-RP) REAGENT

Jul 19, 2002
66 days to decision

K021572 · Product code: **DCN** · Immunology
Source: <https://www.510kdatabase.net/k021572/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, C-reactive Protein (DCN) |
| Date received | May 14, 2002 |
| Decision date | Jul 19, 2002 |
| Days to decision | 66 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | SYNCHRON SYSTEMS CX C-RP 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,...