

**K130122 BECKMAN COULTER IMAGE IMMUNOCHEMISTRY
SYSTEM LOW CONCENTRATION IMMUNOGLOBULIN,
BECKMAN COULTER**Jan 7, 2014
355 days to decisionK130122 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k130122/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Method, Nephelometric, Immunoglobulins (g, A, M) (CFN) |
| Date received | Jan 17, 2013 |
| Decision date | Jan 7, 2014 |
| Days to decision | 355 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Beckman Coulter, Inc. |
| Location | Chaska, MN, US |
| Contact | AMANDA BROWN |
| 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,...