

**K062516 ACCESS THYROGLOBULIN ANTIBODY II ASSAY,  
MODELS A32898 (REAGENT) AND A36920 (CALIBRATORS)**Oct 5, 2006  
38 days to decisionK062516 · Product code: JNL · Immunology  
Source: <https://www.510kdatabase.net/k062516/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Special                                          |
| Device classification | Immunochemical, Thyroglobulin Autoantibody (JNL) |
| Date received         | Aug 28, 2006                                     |
| Decision date         | Oct 5, 2006                                      |
| Days to decision      | 38 days                                          |
| Third-party review    | No                                               |
| Combination product   | No                                               |
| PCCP authorized       | No                                               |
| Summary / Statement   | Summary                                          |

**APPLICANT**

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|----------------|-----------------------------------------------------------------------------|
| Company        | <b>Beckman Coulter, Inc.</b>                                                |
| Location       | Chaska, MN, US                                                              |
| Contact        | TYLER FOUTCH                                                                |
| Website        | <a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a> |
| 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,...