

K112933 ACCESS THYROGLOBULIN ANITBODYDec 27, 2011
85 days to decisionK112933 · Product code: **JNL** · Immunology
Source: <https://www.510kdatabase.net/k112933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunochemical, Thyroglobulin Autoantibody (JNL)
Date received	Oct 3, 2011
Decision date	Dec 27, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	GERALDINE L BAGLIEN
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,...
