FDA 510(k) Premarket Notification

**CLEARED**

# K153651 Access TSH (3RD IS) Assay and Access TSH (3RD IS) Calibrators on the Access Immunoassay Systems

Aug 18, 2016
241 days to decision

K153651 · Product code: **JLW** · Chemistry
Source: https://www.510kdatabase.net/k153651/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Thyroid-stimulating Hormone (JLW) |
| Date received | Dec 21, 2015 |
| Decision date | Aug 18, 2016 |
| Days to decision | 241 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Beckman Coulter, Inc.** |
| Location | Chaska, MN, US |
| Contact | MICHAEL ROBERT LORENZ |
| 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,...