FDA 510(k) Premarket Notification

# K242870 Access hsTnI

**CLEARED**

Jun 16, 2025
266 days to decision

K242870 · Product code: **MMI** · Chemistry
Source: https://www.510kdatabase.net/k242870/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunoassay Method, Troponin Subunit (MMI) |
| Date received | Sep 23, 2024 |
| Decision date | Jun 16, 2025 |
| Days to decision | 266 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## 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,...

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k242870/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026