FDA 510(k) Premarket Notification

# K894238 ABBOTT TDX TOTAL T3 PLUS

**CLEARED**

Oct 31, 1989
132 days to decision

K894238 · Product code: **CDP** · Chemistry
Source: https://www.510kdatabase.net/k894238/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Total Triiodothyronine (CDP) |
| Date received | Jun 21, 1989 |
| Decision date | Oct 31, 1989 |
| Days to decision | 132 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Abbott Laboratories** |
| Location | Abbott Park, IL, US |
| Contact | CAROLYN BAIRSTOW |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...