

K771309 RIA FOR TOTAL THYROXINEAug 3, 1977
16 days to decisionK771309 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k771309/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Total Thyroxine (CDX) |
| Date received | Jul 18, 1977 |
| Decision date | Aug 3, 1977 |
| Days to decision | 16 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Laboratories |
| Location | Abbott Park, IL, US |
| 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...

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