

K803046 IMMU-TRACE T4 RIA PROCEDUREJan 2, 1981
32 days to decisionK803046 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k803046/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Total Thyroxine (CDX) |
| Date received | Dec 1, 1980 |
| Decision date | Jan 2, 1981 |
| Days to decision | 32 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | American Dade |
| Location | Mchenry, IL, US |
| 510(k) history | 149 submissions · 149 cleared · 1980-1987 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k803046/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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