

**K860421 STRAT TOTAL THYROXINE FLUOROMET ENZYME
IMMUNOASSAY**Feb 11, 1986
7 days to decisionK860421 · Product code: **CDX** · Chemistry
Source: <https://www.510kdatabase.net/k860421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Feb 4, 1986
Decision date	Feb 11, 1986
Days to decision	7 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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