

**K862428 STRATUS TSH FLUOROMETRIC ENZYME
IMMUNOASSAY**Aug 19, 1986
54 days to decisionK862428 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k862428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 26, 1986
Decision date	Aug 19, 1986
Days to decision	54 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/k862428/> 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