

K912852 STRATUS(R) ULTRA-SENSIT HTSH FLUOR ENZYME IMMUNO

Sep 27, 1991
91 days to decision

K912852 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k912852/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 28, 1991
Decision date	Sep 27, 1991
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k912852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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