

K914756 ULTRASENSITIVE TSH (U-TSH) ENZYME IMMUNO TEST KIT

Jan 15, 1992
85 days to decision

K914756 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k914756/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Oct 22, 1991
Decision date	Jan 15, 1992
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medix Biotech, Inc.
Location	Redwood City, CA, US
Contact	JOHN CHEN
510(k) history	39 submissions · 39 cleared · 1985-1995

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Device record: <https://www.510kdatabase.net/k914756/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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