

K062581 OLYMPUS TSH REAGENT, CALIBRATOR AND CONTROL AND AU3000I IMMUNOASSAY SYSTEMNov 29, 2006
90 days to decisionK062581 · Product code: JLW · Chemistry
Source: <https://www.510kdatabase.net/k062581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Aug 31, 2006
Decision date	Nov 29, 2006
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	DAVID DAVIS
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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