

**K170232 AFIAS TSH-SP, AFIAS TSH-VB, AFIAS-6/SP Analyzer,
AFIAS-6/VB Analyzer**Oct 13, 2017
261 days to decisionK170232 · Product code: JLW · Chemistry
Source: <https://www.510kdatabase.net/k170232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jan 25, 2017
Decision date	Oct 13, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boditech Med, Inc.
Location	Chuncheon-Si, Gang-Won-Do, KR
Contact	HYUNG-JU OH
510(k) history	2 submissions · 2 cleared · 2014-2017

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