

K131928 FREND TSH (REAGENT CARTRIDGE)Mar 14, 2014
260 days to decisionK131928 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k131928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 27, 2013
Decision date	Mar 14, 2014
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanoentek USA, Inc.
Location	Oxford, CT, US
Contact	JUDITH E LOEBEL
510(k) history	5 submissions · 5 cleared · 2014-2017

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