

**K152422 FREND™ Free T4 Test System**Feb 17, 2016  
175 days to decisionK152422 · Product code: **CEC** · Chemistry  
Source: <https://www.510kdatabase.net/k152422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Aug 26, 2015
Decision date	Feb 17, 2016
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanoentek USA, Inc.</b>
Location	Oxford, CT, US
Contact	JIMMY CHEN
510(k) history	5 submissions · 5 cleared · 2014-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152422/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026