

K124056 FREND PSA PLUS (REAGENT CARTRIDGE)May 29, 2013
149 days to decisionK124056 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k124056/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Dec 31, 2012
Decision date	May 29, 2013
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanoentek, Inc.
Location	Oxford, CT, US
Contact	JUDITH E LOEBEL
510(k) history	1 submissions · 1 cleared · 2013-2013

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