

K162378 FREND PSA PLUS (reagent cartridge)May 17, 2017
266 days to decisionK162378 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k162378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Aug 24, 2016
Decision date	May 17, 2017
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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