

K153577 FREN D Testosterone Test SystemOct 14, 2016
304 days to decisionK153577 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k153577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Dec 15, 2015
Decision date	Oct 14, 2016
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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