

**K101185 NUCLEIC ACID DETECTION IMMUNOASSAY (NADIA)
PSA ASSAY**Sep 20, 2011
510 days to decisionK101185 · Product code: **OWM** · Immunology
Source: <https://www.510kdatabase.net/k101185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Prognostic, Recurrence Risk Assessment Of Prostate Cancers (OWM)
Date received	Apr 28, 2010
Decision date	Sep 20, 2011
Days to decision	510 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iris Molecular Diagnostics
Location	Carlsbad, CA, US
Contact	ROBERT KLEM
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101185/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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