FDA 510(k) Premarket Notification

K050063 PROSTATE-63 CANCER DIAGNOSTIC TEST

CLEARED

Feb 9, 2005
29 days to decision

K050063 · Product code: **NTR** · Pathology
Source: https://www.510kdatabase.net/k050063/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunohistochemical Reagent, Antibody (monoclonal Or Polyclonal) To P63 Protein In Nucleus Of Prostatic Basal Cells (NTR)
Date received	Jan 11, 2005
Decision date	Feb 9, 2005
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asymmetrx**
Location	Amston, CT, US
Contact	MARIA MCKEON
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k050063/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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