

K052519 SPECTRAL WEST NILE VIRUS IGM STATUS TESTNov 30, 2006
442 days to decisionK052519 · Product code: **NOP** · Microbiology
Source: <https://www.510kdatabase.net/k052519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elisa, Antibody, West Nile Virus (NOP)
Date received	Sep 14, 2005
Decision date	Nov 30, 2006
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectral Diagnostics, Inc.
Location	Toronto, Ontario, CA
Contact	NISAR A SHAIKH
510(k) history	12 submissions · 11 cleared · 1997-2006

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