

K031952 WEST NILE VIRUS IGM CAPTURE ELISA, MODEL EL0300M

Oct 22, 2003
119 days to decision

K031952 · Product code: **NOP** · Microbiology
Source: <https://www.510kdatabase.net/k031952/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elisa, Antibody, West Nile Virus (NOP)
Date received	Jun 25, 2003
Decision date	Oct 22, 2003
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Technologies, Inc.
Location	Cypress, CA, US
Contact	MICHAEL J WAGNER
510(k) history	5 submissions · 5 cleared · 2002-2004

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k031952/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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