

K031953 WEST NILE VIRUS ELISA IGG, MODEL EL0300GOct 22, 2003
119 days to decisionK031953 · Product code: **NOP** · Microbiology
Source: <https://www.510kdatabase.net/k031953/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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.netDevice record: <https://www.510kdatabase.net/k031953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026