

**K061360 NEOMARKERS RABBIT MONOCLONAL ANTI-HUMAN
ESTROGEN RECEPTOR ANTIBODY (CLONE SP1)**Jun 27, 2006
42 days to decisionK061360 · Product code: MYA · Pathology
Source: <https://www.510kdatabase.net/k061360/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA) |
| Date received | May 16, 2006 |
| Decision date | Jun 27, 2006 |
| Days to decision | 42 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lab Vision Corp. |
| Location | Fremont, CA, US |
| Contact | GRACE HSIAO-FEN CHANG |
| 510(k) history | 2 submissions · 2 cleared · 2006-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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