FDA 510(k) Premarket Notification

# K891781 TOXO ELISA TEST SYSTEM

**CLEARED**

Jul 14, 1989
112 days to decision

K891781 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k891781/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD) |
| Date received | Mar 24, 1989 |
| Decision date | Jul 14, 1989 |
| Days to decision | 112 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Zeus Scientific, Inc.** |
| Location | Mchenry, IL, US |
| Contact | JERRY W PICKERING |
| Website | https://www.zeusscientific.com |
| 510(k) history | 135 submissions · 135 cleared · 1976-2022 |

Zeus Scientific, Inc. is a chemistry and immunology device manufacturer based in McHenry, US. The company specializes in flexible autoimmune and infectious disease testing solutions. Zeus Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's regulatory portfolio spans microbiology devices and immunology testing systems, including ELISA-based assays and immunofluorescence platforms. The latest clearance on record dates to 2022, reflecting the company's historical contribution to diagnostic device development. ...