

K983804 THE APTUS (AUTOMATED) APPLICATION OF THE EBV-EA IGG ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FORDec 8, 1998
41 days to decisionK983804 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k983804/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Epstein-barr Virus, Other (LSE) |
| Date received | Oct 28, 1998 |
| Decision date | Dec 8, 1998 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Zeus Scientific, Inc. |
| Location | Mchenry, IL, US |
| Contact | MARK J KOPNITSKY |
| 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. ...