

K833014 EBV-VCA-IGM IFA TEST SYSTEMDec 27, 1983
112 days to decisionK833014 · Product code: **LJN** · Immunology
Source: <https://www.510kdatabase.net/k833014/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antibody Igm, If, Epstein-barr Virus (LJN) |
| Date received | Sep 6, 1983 |
| Decision date | Dec 27, 1983 |
| Days to decision | 112 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Zeus Scientific, Inc. |
| Location | Mchenry, IL, US |
| 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. ...

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Device record: <https://www.510kdatabase.net/k833014/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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