

K841434 VARICELLA-ZOSTER(IGG) IFA TESTApr 19, 1985
378 days to decisionK841434 · Product code: **GQW** · Microbiology
Source: <https://www.510kdatabase.net/k841434/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigen, Cf, (including Cf Control), Varicella-zoster (GQW) |
| Date received | Apr 6, 1984 |
| Decision date | Apr 19, 1985 |
| Days to decision | 378 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Zeus Scientific, Inc. |
| Location | Mchenry, IL, US |
| Contact | DAVID A WALL |
| 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. ...
