

K964449 ANCA SCREEN ELISA TEST SYSTEMApr 10, 1997
155 days to decisionK964449 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k964449/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received | Nov 6, 1996 |
| Decision date | Apr 10, 1997 |
| Days to decision | 155 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. ...
