

K984034 THE APTUS (AUTOMATED) APPLICATION OF THE ANCA SCREEN ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FORNov 30, 1998
18 days to decisionK984034 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k984034/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received | Nov 12, 1998 |
| Decision date | Nov 30, 1998 |
| Days to decision | 18 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. ...