FDA 510(k) Premarket Notification

**CLEARED**

# K102425 ZEUS ELISA CARDIOLIPIN IGG/IGM/IGA TEST SYSTEM

Dec 12, 2011
474 days to decision

K102425 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k102425/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Anticardiolipin Immunological (MID) |
| Date received | Aug 25, 2010 |
| Decision date | Dec 12, 2011 |
| Days to decision | 474 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Zeus Scientific, Inc.** |
| Location | Mchenry, IL, US |
| Contact | EWA NADOLCZAK |
| 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. ...