

**K941409 ENA PROFILE-6 ELISA TEST SYSTEM**Jun 10, 1994  
79 days to decisionK941409 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k941409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 23, 1994
Decision date	Jun 10, 1994
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Zeus Scientific, Inc.</b>
Location	Mchenry, IL, US
Contact	MARK J KOPNITSKY
Website	<a href="https://www.zeusscientific.com">https://www.zeusscientific.com</a>
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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