CLEARED

K983422 THE APTUS (AUTOMATED) APPLICATIONS OF THE DS DNA ELISA TEST SYSTEM LINKED IMMUNOSORBENT ASSAY(ELISA)FOR THE DET

Nov 18, 1998
50 days to decision

K983422 · Product code: **LRM** · Immunology
Source: https://www.510kdatabase.net/k983422/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Sep 29, 1998
Decision date	Nov 18, 1998
Days to decision	50 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. ...