

K983805 THE APTUS (AUTOMATED) APPLICATION OF THE RUBELLA IGG ELISA TEST SYSTEM. AN ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOMay 26, 1999
210 days to decisionK983805 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k983805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Oct 28, 1998
Decision date	May 26, 1999
Days to decision	210 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. ...