FDA 510(k) Premarket Notification

K831358 AUTOANTIBODY SCREEN TEST SYSTEM

CLEARED

Jun 15, 1983
50 days to decision

K831358 · Product code: **DBM** · Microbiology
Source: https://www.510kdatabase.net/k831358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM)
Date received	Apr 26, 1983
Decision date	Jun 15, 1983
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Zeus Scientific, Inc.**
Location	Mchenry, IL, US
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. ...