

K897025 ANTINUCLEAR ANTIBODY (ANA) TEST SYSTEMJan 2, 1990
14 days to decisionK897025 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k897025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Dec 19, 1989
Decision date	Jan 2, 1990
Days to decision	14 days
Third-party review	No

APPLICANT

Company	Zeus Scientific, Inc.
Location	McHenry, IL, US
Contact	DONALD R TOURVILLE
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. ...