

K821060 FLUORO-CEPJun 22, 1982
68 days to decision

K821060 · Chemistry

Source: <https://www.510kdatabase.net/k821060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Apr 15, 1982
Decision date	Jun 22, 1982
Days to decision	68 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. ...