

K811671 CYTOMEGALOVIRUS ANTIBODY TEST SYSTEMSep 16, 1981
93 days to decisionK811671 · Product code: **GQH** · Microbiology
Source: <https://www.510kdatabase.net/k811671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	Jun 15, 1981
Decision date	Sep 16, 1981
Days to decision	93 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. ...

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Device record: <https://www.510kdatabase.net/k811671/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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