

K791385 NEGATIVE CONTROL SERUM FOR CF RO IDAug 16, 1979
36 days to decisionK791385 · Product code: **GSN** · Microbiology
Source: <https://www.510kdatabase.net/k791385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Positive And Negative Febrile Antigen Control Serum (GSN)
Date received	Jul 11, 1979
Decision date	Aug 16, 1979
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Immuno-Mycologics, Inc.
Location	Mchenry, IL, US
510(k) history	26 submissions · 26 cleared · 1979-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k791385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 2, 2026