

K800228 IMMUNOP. ANTISMOOTH MUSCLE ANTIBODY KITFeb 21, 1980
16 days to decisionK800228 · Product code: **DBE** · Immunology
Source: <https://www.510kdatabase.net/k800228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antismooth Muscle Antibody, Indirect Immunofluorescent, Antigen, Control (DBE)
Date received	Feb 5, 1980
Decision date	Feb 21, 1980
Days to decision	16 days
Third-party review	No

APPLICANT

Company	Clinical Sciences, Inc.
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1977-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k800228/> 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 June 30, 2026