

K800451 GEMENI IGG ASSAYApr 24, 1980
55 days to decisionK800451 · Product code: **DEW** · Immunology
Source: <https://www.510kdatabase.net/k800451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Feb 29, 1980
Decision date	Apr 24, 1980
Days to decision	55 days
Third-party review	No

APPLICANT

Company	Electro-Nucleonics Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1976-1988

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Device record: <https://www.510kdatabase.net/k800451/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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