FDA 510(k) Premarket Notification

K800450 GEMENI IGM ASSAY

CLEARED

Apr 24, 1980
55 days to decision

K800450 · Product code: **DAO** · Immunology
Source: https://www.510kdatabase.net/k800450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm (mu Chain Specific), Antigen, Antiserum, Control (DAO)
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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k800450/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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