FDA 510(k) Premarket Notification

# K800449 GEMENI IGA ASSAY

**CLEARED**

Mar 12, 1980
12 days to decision

K800449 · Product code: **CZP** · Immunology
Source: https://www.510kdatabase.net/k800449/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Iga, Antigen, Antiserum, Control (CZP) |
| Date received | Feb 29, 1980 |
| Decision date | Mar 12, 1980 |
| Days to decision | 12 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/k800449/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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