FDA 510(k) Premarket Notification

K831965 CREATINE KINASE REAGENT CK LTS

CLEARED

Sep 12, 1983
84 days to decision

K831965 · Product code: **CGS** · Chemistry
Source: https://www.510kdatabase.net/k831965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Jun 20, 1983
Decision date	Sep 12, 1983
Days to decision	84 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/k831965/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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