

K821199 CREATININE REAGENT SETJul 13, 1982
77 days to decisionK821199 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k821199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Apr 27, 1982
Decision date	Jul 13, 1982
Days to decision	77 days
Third-party review	No

APPLICANT

Company	Omega Medical Electronics
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1982-1983

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821199/> 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 29, 2026