

**K864359 CK-NAC REAGENT(CREATINE KINASE/N-ACETYL
CYSTEINE)**Feb 6, 1987
95 days to decisionK864359 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k864359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Nov 3, 1986
Decision date	Feb 6, 1987
Days to decision	95 days
Third-party review	No

APPLICANT

Company	Trace Scientific , Ltd.
Location	Clayton, Vic 3168, AU
Contact	WILLIAM C RIDDLE
510(k) history	55 submissions · 55 cleared · 1986-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864359/> 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