

K974833 CK-NAC REAGENTFeb 13, 1998
51 days to decisionK974833 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k974833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Dec 24, 1997
Decision date	Feb 13, 1998
Days to decision	51 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Intersect Systems, Inc.
Location	Mchenry, IL, US
Contact	MARK E LEGAZ
510(k) history	21 submissions · 21 cleared · 1983-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974833/> 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 30, 2026