

**K973999 CREATINE KINASE-SL ASSAY, CATALOGUE NUMBER
326-10, 326-30**Mar 11, 1998
141 days to decisionK973999 · Product code: **CGS** · Chemistry
Source: <https://www.510kdatabase.net/k973999/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Oct 21, 1997
Decision date	Mar 11, 1998
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Chemicals , Ltd.
Location	Charlottetown, P.E.I., CA
Contact	KAREN CALLBECK
510(k) history	66 submissions · 66 cleared · 1994-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973999/> 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 28, 2026