

**K993178 UREA-L3K ASSAY, CATALOGUE NUMBER
283-17/10/30/50**Oct 18, 1999
25 days to decisionK993178 · Product code: **CDQ** · Chemistry
Source: <https://www.510kdatabase.net/k993178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Sep 23, 1999
Decision date	Oct 18, 1999
Days to decision	25 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/k993178/> 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