

K001285 AMMONIA-L3K ASSAY, MODEL 263-17, AMMONIA-L3K ASSAY, MODEL 263-30Jun 2, 2000
42 days to decisionK001285 · Product code: JIF · Chemistry
Source: <https://www.510kdatabase.net/k001285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Ammonia (JIF)
Date received	Apr 21, 2000
Decision date	Jun 2, 2000
Days to decision	42 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/k001285/> 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