

K974053 AMYLASE-SL ASSAY CATALOGUE NUMBER 341-10Dec 8, 1997
42 days to decisionK974053 · Product code: **JFJ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Oct 27, 1997
Decision date	Dec 8, 1997
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

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