

**K945243 CATALOGUE NUMBER 321-07/15/50**Feb 8, 1995  
104 days to decisionK945243 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k945243/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Oct 27, 1994
Decision date	Feb 8, 1995
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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