

K070383 ENZYMATIC CREATININE ASSAY (265 SERIES)Jun 22, 2007
133 days to decisionK070383 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k070383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Feb 9, 2007
Decision date	Jun 22, 2007
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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