

K061944 POLY-CHEM CREATININENov 3, 2006
116 days to decisionK061944 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k061944/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jul 10, 2006
Decision date	Nov 3, 2006
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

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