

K944229 OLYMPUS AMYLASE REAGENTDec 9, 1994
100 days to decisionK944229 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k944229/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Aug 31, 1994
Decision date	Dec 9, 1994
Days to decision	100 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	LAURA STORMS-TYLER
510(k) history	149 submissions · 149 cleared · 1994-2012

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