

K011169 HSCRCP CONTROL LEVEL 1, HSCRCP CONTROL LEVEL 2, AND HSCRCP CONTROL LEVEL 3May 18, 2001
31 days to decisionK011169 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k011169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Apr 17, 2001
Decision date	May 18, 2001
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	International Enzymes, Inc.
Location	Fallbrook, CA, US
Contact	CAROL RUGGIERO
510(k) history	7 submissions · 7 cleared · 1994-2001

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