

K965166 STABLELIN ENZYME LINERARITY TEST SET A (ITEM NO. 001)

Feb 4, 1997
42 days to decision

K965166 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k965166/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Dec 24, 1996
Decision date	Feb 4, 1997
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Specialized Assays, Inc.
Location	Pipersville, PA, US
Contact	RICHARD A KAUFMAN
510(k) history	3 submissions · 3 cleared · 1997-1997

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Device record: <https://www.510kdatabase.net/k965166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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