

K971761 PERSONALLAB AUTOMATED MICROPLATE ANALYZERJul 22, 1997
71 days to decisionK971761 · Product code: **JJE** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	May 12, 1997
Decision date	Jul 22, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biochem Immunosystems (U.S.), Inc.
Location	Allentown, PA, US
Contact	JAMES SAFRANKO
510(k) history	4 submissions · 4 cleared · 1996-1997

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