

K964527 N RHEUMATOLOGY STANDARD SLJan 15, 1997
64 days to decisionK964527 · Product code: **JIX** · Immunology
Source: <https://www.510kdatabase.net/k964527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Nov 12, 1996
Decision date	Jan 15, 1997
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	Ruth Forstadt
510(k) history	145 submissions · 145 cleared · 1976-1997

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