

**K964315 REMEL STAPH LATEX KIT**Feb 7, 1997  
101 days to decisionK964315 · Product code: **JWX** · Microbiology  
Source: <https://www.510kdatabase.net/k964315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Staphylococcus Aureus (JWX)
Date received	Oct 29, 1996
Decision date	Feb 7, 1997
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Remel, L.P.</b>
Location	Lenexa, KS, US
Contact	DAVID A WALL
510(k) history	10 submissions · 10 cleared · 1996-1997

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