

**K912391 RUBALEX, MODIFICATION**May 4, 1992  
346 days to decisionK912391 · Product code: **LQN** · Microbiology  
Source: <https://www.510kdatabase.net/k912391/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Agglutination Assay, Rubella (LQN)
Date received	May 24, 1991
Decision date	May 4, 1992
Days to decision	346 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orion Corp.</b>
Location	20101 Turku, FI
Contact	TIMO RAINES
510(k) history	21 submissions · 20 cleared · 1985-1992

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