

**K915320 RHEUMA-LEX(TM) SYST: RHEUMATOID FACTOR  
LATEX TEST**Dec 7, 1992  
381 days to decisionK915320 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k915320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Nov 22, 1991
Decision date	Dec 7, 1992
Days to decision	381 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trinity Laboratories, Inc.</b>
Location	Raleigh, NC, US
Contact	BRUCE A CLINTON
510(k) history	44 submissions · 28 cleared · 1990-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915320/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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