

**K896433 MODIFIED RUBAGEN**Nov 29, 1989  
20 days to decisionK896433 · Product code: **LQN** · Microbiology  
Source: <https://www.510kdatabase.net/k896433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Agglutination Assay, Rubella (LQN)
Date received	Nov 9, 1989
Decision date	Nov 29, 1989
Days to decision	20 days
Third-party review	No

**APPLICANT**

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Company	<b>Biokit USA, Inc.</b>
Location	Mchenry, IL, US
Contact	IGNACIO ODRIUZOLA
510(k) history	16 submissions · 16 cleared · 1984-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896433/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026