

**K893897 SEMI-QUANTITATIVE ASSAY FOR DET. OF IGG AND IGM**Jun 23, 1989  
24 days to decisionK893897 · Product code: **LKJ** · Immunology  
Source: <https://www.510kdatabase.net/k893897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	May 30, 1989
Decision date	Jun 23, 1989
Days to decision	24 days
Third-party review	No

**APPLICANT**

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Company	<b>Biostar Medical Products, Inc.</b>
Location	Denver, CO, US
Contact	JERRY BERKSTRESSER
510(k) history	5 submissions · 5 cleared · 1985-1989

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k893897/>; 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