

**K882999 RUBENOSTIKA(TM) IGM MICROELISA SYSTEM**Jan 31, 1989  
197 days to decisionK882999 · Product code: LFX · Microbiology  
Source: <https://www.510kdatabase.net/k882999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jul 18, 1988
Decision date	Jan 31, 1989
Days to decision	197 days
Third-party review	No

**APPLICANT**

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Company	<b>Organon Teknika Corp.</b>
Location	Mchenry, IL, US
Contact	TONI M STIFANO
510(k) history	130 submissions · 129 cleared · 1980-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k882999/>; 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 May 22, 2026