

**K950227 RUBELISA (RUBESTAT)**Aug 15, 1995  
217 days to decisionK950227 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k950227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jan 10, 1995
Decision date	Aug 15, 1995
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Whittaker, Inc., A Cambrex Co.</b>
Location	Walkersville, MD, US
Contact	LEIF E OLSEN
510(k) history	3 submissions · 3 cleared · 1995-1997

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