

**K912371 BIOMERIEUX RSV DIRECT IF KIT**Sep 23, 1991  
117 days to decisionK912371 · Product code: **LKT** · Microbiology  
Source: <https://www.510kdatabase.net/k912371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
Date received	May 29, 1991
Decision date	Sep 23, 1991
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Vitek Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	CHERYL WINTERS-HEARD
510(k) history	39 submissions · 39 cleared · 1978-1993

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