

**K842047 ORTHO\* RSV ANTIGEN ELISA TEST SYS**Oct 5, 1984  
137 days to decisionK842047 · Product code: **LKT** · Microbiology  
Source: <https://www.510kdatabase.net/k842047/>**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 21, 1984
Decision date	Oct 5, 1984
Days to decision	137 days
Third-party review	No

**APPLICANT**

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Company	<b>Ortho Diagnostic Systems, Inc.</b>
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k842047/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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