

**K841527 ORTHO RESPIRATORY SYNCYTIAL VIRUS-**Aug 12, 1984  
122 days to decisionK841527 · Product code: **LKT** · Microbiology  
Source: <https://www.510kdatabase.net/k841527/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
Date received	Apr 12, 1984
Decision date	Aug 12, 1984
Days to decision	122 days
Third-party review	No

**APPLICANT**

---

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

---

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

Device record: <https://www.510kdatabase.net/k841527/> 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 14, 2026