

**K081928 D3 DUET DFA RSV/RESPIRATORY VIRUS SCREENING
KIT**Dec 23, 2008
169 days to decisionK081928 · Product code: **LKT** · Microbiology
Source: <https://www.510kdatabase.net/k081928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Syncytial Virus, Antigen, Antibody, Ifa (LKT)
Date received	Jul 7, 2008
Decision date	Dec 23, 2008
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostic Hybrids, Inc.
Location	Athens, OH, US
Contact	GAIL R GOODRUM
510(k) history	37 submissions · 36 cleared · 1988-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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