FDA 510(k) Premarket Notification

CLEARED

K091171 D3 ULTRA DUET DFA RESPIRATORY VIRUS IDENTIFICATION KIT

Sep 11, 2009
142 days to decision

K091171 · Product code: **OMG** · Microbiology
Source: https://www.510kdatabase.net/k091171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, Human Metapneumovirus (OMG)
Date received	Apr 22, 2009
Decision date	Sep 11, 2009
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostic Hybrids, Inc.**
Location	Athens, OH, US
Contact	Ronald H Lollar
510(k) history	37 submissions · 36 cleared · 1988-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091171/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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