K063675 DIAGNOSTIC HYBRIDS' D3 DFA CHLAMYDIAE CULTURE CONFIRMATION KIT

CLEARED

Sep 24, 2007
287 days to decision

K063675 · Product code: **LJP** · Microbiology
Source: https://www.510kdatabase.net/k063675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Fluorescent, Chlamydia Trachomatis (LJP)
Date received	Dec 11, 2006
Decision date	Sep 24, 2007
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k063675/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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