

**K081164 D3 DFA CYTOMEGALOVIRUS IMMEDIATE EARLY
ANTIGEN IDENTIFICATION KIT**Jun 13, 2008
50 days to decisionK081164 · Product code: **LIN** · Microbiology
Source: <https://www.510kdatabase.net/k081164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Conjugated Fluorescent, Cytomegalovirus (LIN)
Date received	Apr 24, 2008
Decision date	Jun 13, 2008
Days to decision	50 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

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