FDA 510(k) Premarket Notification

K090073 D3 DFA METAPNEUMOVIRUS IDENTIFICATION KIT

CLEARED

Mar 6, 2009
53 days to decision

K090073 · Product code: **OMG** · Microbiology
Source: https://www.510kdatabase.net/k090073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, Human Metapneumovirus (OMG)
Date received	Jan 12, 2009
Decision date	Mar 6, 2009
Days to decision	53 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