FDA 510(k) Premarket Notification

K093415 D3 FASTPOINT L-DFA PARAINFLUENZA VIRUS/ADENOVIRUS IDENTIFICATION KIT

CLEARED

Dec 23, 2009
51 days to decision

K093415 · Product code: **GQS** · Microbiology
Source: https://www.510kdatabase.net/k093415/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Cf (including Cf Control), Parainfluenza Virus 1-4 (GQS)
Date received	Nov 2, 2009
Decision date	Dec 23, 2009
Days to decision	51 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