FDA 510(k) Premarket Notification

K061101 D3 ULTRA DFA RESPIRATORY VIRUS SCREENING & ID KIT

CLEARED

Nov 20, 2006
214 days to decision

K061101 · Product code: **GNW** · Microbiology
Source: https://www.510kdatabase.net/k061101/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Cf, Influenza Virus A, B, C (GNW)
Date received	Apr 20, 2006
Decision date	Nov 20, 2006
Days to decision	214 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