FDA 510(k) Premarket Notification

K081746 D3 DUET DFA INFLUENZA A/RESPIRATORY VIRUS SCREENING KIT

CLEARED

Dec 23, 2008
187 days to decision

K081746 · Product code: **GNW** · Microbiology
Source: https://www.510kdatabase.net/k081746/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Cf, Influenza Virus A, B, C (GNW)
Date received	Jun 19, 2008
Decision date	Dec 23, 2008
Days to decision	187 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