

**K081746 D3 DUET DFA INFLUENZA A/RESPIRATORY VIRUS  
SCREENING KIT**Dec 23, 2008  
187 days to decisionK081746 · 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	<b>Diagnostic Hybrids, Inc.</b>
Location	Athens, OH, US
Contact	GAIL R GOODRUM
510(k) history	37 submissions · 36 cleared · 1988-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081746/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026