

K092500 MODIFICATION TO PROFLU+ ASSAYAug 20, 2009
6 days to decisionK092500 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k092500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Aug 14, 2009
Decision date	Aug 20, 2009
Days to decision	6 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Prodesse, Inc.
Location	Waukesha, WI, US
Contact	KRISTINE SCHRAUFNAGEL
510(k) history	6 submissions · 6 cleared · 2008-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092500/> Data sourced from FDA 510(k) public records (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. - Generated June 22, 2026