

K081030 MODIFICATION TO PROFLU+ ASSAYMay 2, 2008
21 days to decisionK081030 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k081030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Apr 11, 2008
Decision date	May 2, 2008
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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