

K101855 PROFAST+ ASSAYJul 23, 2010
22 days to decisionK101855 · Product code: **OQW** · Microbiology
Source: <https://www.510kdatabase.net/k101855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Jul 1, 2010
Decision date	Jul 23, 2010
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gen-Probe Prodesse, Inc.
Location	Waukesha, WI, US
Contact	KAREN HARRINGTON
510(k) history	10 submissions · 10 cleared · 2010-2013

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