FDA 510(k) Premarket Notification

K132237 PRODESSE PROFAST+ ASSAY

CLEARED

Aug 26, 2013
39 days to decision

K132237 · Product code: **OQW** · Microbiology
Source: https://www.510kdatabase.net/k132237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Jul 18, 2013
Decision date	Aug 26, 2013
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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