FDA 510(k) Premarket Notification

K090239 PROGASTRO CD ASSAY

CLEARED

Apr 16, 2009
73 days to decision

K090239 · Product code: **LLH** · Microbiology
Source: https://www.510kdatabase.net/k090239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Feb 2, 2009
Decision date	Apr 16, 2009
Days to decision	73 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