

K110605 ROM PLUSNov 23, 2011
266 days to decisionK110605 · Product code: **NQM** · Chemistry
Source: <https://www.510kdatabase.net/k110605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay For Detection Of Amniotic Fluid Protein(s). (NQM)
Date received	Mar 2, 2011
Decision date	Nov 23, 2011
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clinical Innovations, LLC
Location	Murray, UT, US
Contact	DEAN WALLACE
510(k) history	9 submissions · 9 cleared · 2007-2025

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