

**K081767 AMNISURE FETAL MEMBRANES RUPTURE TEST,
MODEL FMRT-1**Jan 9, 2009
203 days to decisionK081767 · Product code: **NQM** · Chemistry
Source: <https://www.510kdatabase.net/k081767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay For Detection Of Amniotic Fluid Protein(s). (NQM)
Date received	Jun 20, 2008
Decision date	Jan 9, 2009
Days to decision	203 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Amnisure International, LLC
Location	Cambridge, MA, US
Contact	MICHAEL FRIEDMAN
510(k) history	1 submissions · 1 cleared · 2009-2009

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