

**K030849 AMNISURE FETAL MEMBRANES RUPTURE TEST  
MODEL FMRT1**Feb 2, 2004  
322 days to decisionK030849 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k030849/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 17, 2003
Decision date	Feb 2, 2004
Days to decision	322 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>N-Dia, Inc.</b>
Location	New York, NY, US
Contact	MICHAEL FRIEDMAN
510(k) history	1 submissions · 1 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030849/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026