FDA 510(k) Premarket Notification

K030849 AMNISURE FETAL MEMBRANES RUPTURE TEST MODEL FMRT1

CLEARED

Feb 2, 2004
322 days to decision

K030849 · Product code: **JJX** · Chemistry
Source: https://www.510kdatabase.net/k030849/

SUBMISSION DETAILS

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

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