

K911846 URI-THREE(TM), MODIFICATIONOct 4, 1991
169 days to decisionK911846 · Product code: **JXA** · Microbiology
Source: <https://www.510kdatabase.net/k911846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Urine (JXA)
Date received	Apr 18, 1991
Decision date	Oct 4, 1991
Days to decision	169 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Culture Kits, Inc.
Location	Norwich, NY, US
Contact	HOLLY L SWEET
510(k) history	9 submissions · 9 cleared · 1985-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911846/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026