

K954685 URITEST - NITRITE IN URINE TESTJul 22, 1996
285 days to decisionK954685 · Product code: **JMT** · Chemistry
Source: <https://www.510kdatabase.net/k954685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo (colorimetric), Nitrite (urinary, Non-quant) (JMT)
Date received	Oct 11, 1995
Decision date	Jul 22, 1996
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tcpi, Inc.
Location	Ft. Lauderdale, FL, US
Contact	FRAN WHITE
510(k) history	14 submissions · 14 cleared · 1992-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k954685/> 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 28, 2026