FDA 510(k) Premarket Notification

CLEARED

K952096 ONE STEP URINE DRUG OF ABUSE OPIATE TEST (OPIUM/HEROIN/MORPHINE)

Aug 17, 1995
105 days to decision

K952096 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k952096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 4, 1995
Decision date	Aug 17, 1995
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tcpi, Inc.**
Location	Ft. Lauderdale, FL, US
Contact	CLEVE W LAIRD
510(k) history	14 submissions · 14 cleared · 1992-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k952096/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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