FDA 510(k) Premarket Notification

K972405 QUIKPAC II ONE STEP OPIATE TEST

CLEARED

Aug 8, 1997
43 days to decision

K972405 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k972405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 26, 1997
Decision date	Aug 8, 1997
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Drial Consultants, Inc.**
Location	Menlo Park, CA, US
Contact	CLEVE W LAIRD
510(k) history	13 submissions · 13 cleared · 1997-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972405/ 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