

**K994398 INSTANT-VIEW COCAINE (BENZYLECGONINE) URINE
CASSETTE TEST**Jul 27, 2000
212 days to decisionK994398 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k994398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Dec 28, 1999
Decision date	Jul 27, 2000
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Scientific Designs, Inc.
Location	Poway, CA, US
Contact	NAISHU WANG
510(k) history	43 submissions · 43 cleared · 1999-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994398/> 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