

K103227 ORATECT ORAL FLUID DRUG SCREEN DEVICESApr 11, 2012
527 days to decisionK103227 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k103227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Nov 1, 2010
Decision date	Apr 11, 2012
Days to decision	527 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Branan Medical Corporation
Location	Irvine, CA, US
Contact	HUIYING WANG
510(k) history	11 submissions · 11 cleared · 2000-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103227/> 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 15, 2026